

2014-1533

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

ALIGN TECHNOLOGY, INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

and

**CLEARCORRECT OPERATING, LLC and
CLEARCORRECT PAKISTAN (PRIVATE), LTD.,**

Intervenors.

**Appeal from the United States International Trade Commission in
Investigation No. 337-TA-833.**

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1. The full name of every party or amicus represented by me is:
Align Technology, Inc.
2. The name of the real party in interest represented by me is:
Align Technology, Inc.
3. Align Technology, Inc. has no parent corporations, and no publicly held company owns 10 percent or more of the stock of Align Technology, Inc.
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INTRODUCTION

Align Technology, Inc. (“Align”) designs, makes, and sells clear dental aligners — a pioneering way of treating dental misalignment. Align’s dental aligners, developed and marketed as the Invisalign System, are protected by numerous United States patents, including patents directed to the processes by which incremental sets of aligners are digitally designed and physically created, and patents directed to the output of the digital design process itself — digital data sets and treatment plans.

In an arrangement the presiding Administrative Law Judge (“ALJ”) called “a sham,” Intervenors ClearCorrect Operating, Inc. (“ClearCorrect USA”) and ClearCorrect Pakistan (Private), Ltd. (“ClearCorrect Pakistan”) (collectively, “Intervenors” or “ClearCorrect”) attempted to structure their operations so as to evade infringement liability. Specifically, ClearCorrect Pakistan took on the digital design steps of Align’s process claims and created digital data sets (or treatment plans) representative of the individual incremental physical aligners, which were then electronically transmitted to ClearCorrect USA. ClearCorrect USA then undertook the physical creation steps of Align’s process claims by using these digital data sets to mold, and ultimately sell, incremental aligners in the United States.

After lengthy proceedings, the United States International Trade

Commission (“the Commission”) found that Intervenors violate section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, by importing into the United States, selling for importation, and selling in the United States after importation “articles that infringe” valid and enforceable patents held by Align. The Commission first correctly concluded, after a thorough analysis of its governing statute and an extensive solicitation of public comments, that section 337’s prohibition on “importation … of articles” encompasses Intervenors’ electronic transmission into the United States of the accused digital data products. The Commission then correctly rejected Intervenors’ claim construction, invalidity, and estoppel contentions, and found a violation of section 337 with respect to many of Align’s asserted patent claims. The Commission entered cease-and-desist orders that sought to put an end to Intervenors’ infringing activities, with an exception for the treatment of current dental patients in the United States. This Court should affirm (in a concurrent appeal filed by Intervenors, No. 2014-1527) the Commission’s violation findings and these remedial orders.

The Commission, however, made two errors of law on specific issues of first impression before the Commission and this Court, and consequently found no violation of some of Align’s asserted claims. First, with respect to its violation analysis for three apparatus claims directed to treatment plans, the Commission adopted an artificially narrow temporal construction of the term “importation” in

section 337 limiting it to the moment of cross-border transmission of the treatment plans. Based on this erroneous construction, the Commission incorrectly concluded that the treatment plans do not satisfy the asserted claim limitation of being stored on a computer readable medium “at the time of importation.” Such a narrow temporal limitation is improper because the term “importation” denotes the entire act of “bringing” a product into the United States, and the fundamental goal of importation is to introduce the article into the country and make it available in the United States. *See Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923). Just as physical goods are deemed imported when unloaded and stored, not at the moment when they cross the territorial boundaries of the United States, *United States v. Commodities Export Co.*, 972 F.2d 1266, 1269 (Fed. Cir. 1992), the act of bringing electronically transmitted digital data into the United States necessarily includes the act of storing it on a computer or a server in the United States at the conclusion of importation. There is no dispute that Intervenors’ digital data sets are stored on ClearCorrect USA’s servers when they are electronically transmitted into the United States. This Court should bring the Commission’s decision in line with the understanding of importation adopted by courts and other federal agencies, and foreclose an easy avenue of evading section 337’s prohibition on infringing importation.

Second, the Commission erred in holding that the Patent Act provision

defining direct product-by-process infringement, 35 U.S.C. § 271(g), cannot be utilized to show the requisite infringement in Commission proceedings under 19 U.S.C. § 1337. This conclusion contradicts the plain language of section 337, which encompasses all acts of infringement defined in the Patent Act, and misapprehends the statutory scheme. The Commission's conclusion that Congress implicitly exempted infringement under section 271(g) from the ambit of section 337 rests on a misreading of 35 U.S.C. § 271(g) and of this Court's decision in *Kinik Co. v. ITC*, 362 F.3d 1359 (Fed. Cir. 2004), which limits only the applicability of certain section 271(g) defenses in certain section 337 proceedings. This Court should correct the Commission's erroneous interpretation, and vindicate the congressional intent of giving U.S. patent-holders full protection against infringing acts of importation or sales for or after importation.

STATEMENT OF RELATED CASES

This appeal is related to another pending Federal Circuit appeal (No. 2014-1527) filed by the Intervenors in this appeal, ClearCorrect USA. and ClearCorrect Pakistan. Both appeals arise from the same investigation by the United States International Trade Commission, Inv. No. 337-TA-833. On August 7, 2014, this Court entered an order that the two appeals be treated as companion cases and assigned to the same merits panel for oral argument.

This appeal is also related to pending Commission Investigation No. 337-TA-562, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*. This Court previously considered Align's appeal from that investigation in *Align Technology, Inc. v. ITC*, Nos. 2013-1240, -1363 (consolidated). On July 18, 2014, the Court vacated the Commission's decision and remanded. Judge Chen wrote the opinion, joined by Chief Judge Prost. The panel originally included former Chief Judge Rader, who retired from the Court prior to the opinion's issuance and did not participate in the decision. The Court denied a petition for *en banc* rehearing on September 17, 2014. The opinion is not yet reported in the Federal Reporter, but is available in the Westlaw database at 2014 WL 3537066.

This appeal is also related to *Align Technology, Inc. v. ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC*, No. CGC-11-

508603, which is pending in the Superior Court of the State of California, County of San Francisco, and *Align Technology, Inc. v. ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC*, No. 4:11-cv-00695, which is pending in the United States District Court for the Southern District of Texas, Houston Division.

JURISDICTION

The Commission had jurisdiction under 19 U.S.C. § 1337, and its decision, entered on April 3, 2014, constitutes a final and appealable determination. Align timely sought review by this Court on June 2, 2014. This Court has jurisdiction under 28 U.S.C. § 1295(a)(6).

STATEMENT OF ISSUES

The issues presented are:

1. Whether the Commission erred in finding that 19 U.S.C. § 1337 is not violated where the imported infringing articles are not stored on a “computer readable storage media” (as required by patent claims) during electronic transmission, even though the act of importation necessarily includes placing the infringing articles on the requisite storage media.
2. Whether the Commission erred in holding that infringement under 35 U.S.C. § 271(g) cannot form the basis of a violation under 19 U.S.C. § 1337(a)(1)(B)(i).

STATEMENT OF THE CASE AND THE FACTS

The Commission found a violation of section 337, 19 U.S.C. § 1337, by respondents below (and Intervenors in this Court), ClearCorrect USA and ClearCorrect Pakistan, with respect to various claims of five patents held by Align. JA214. The Commission issued cease-and-desist orders directed to Intervenors and terminated the investigation. JA214. On June 2, 2014, the Commission stayed the cease-and-desist orders pending ClearCorrect's appeal to this Court. JA101518.

A. Treatment of Dental Misalignment and Align's Innovative Invisalign System.

Align is a Delaware corporation based in San Jose, California, that designs, develops, manufactures, and markets clear aligners to treat malocclusion — *i.e.*, teeth misalignment. JA2024; JA95615; JA96976. Conventionally, dental professionals have treated malocclusion primarily with metal archwires and brackets, commonly referred to as braces. JA199.155; JA179-180; JA2025-2026; JA96976. Braces, however, contain many limitations and disadvantages. For instance, braces trap food and can result in permanent discoloration of teeth, compromising a dental patient's appearance and hygiene. JA2026-28; JA95768-98. Braces can also cause oral discomfort, tooth decay, and periodontal damage. JA2026-27; JA95796-98.

To overcome the problems associated with conventional orthodontic

treatment, Align conceived and developed its Invisalign System. JA2028; JA95795-97. The Invisalign System, which is based on Align's patented technology, uses a series of clear dental aligners — incremental positioning adjustment appliances that are worn sequentially over a fixed time period to adjust the position of a patient's teeth. JA2033-34; JA95615; JA95995. Dental aligners are plastic devices used to move a patient's teeth from a crooked initial position to a straightened desired configuration. JA2033-34; JA95995. The movements are broken up into incremental stages, with a different aligner worn at each stage. JA2033-34; JA95995. When initially placed on a patient's teeth, the aligner's cavities (or tooth receptacles) are slightly out of line with the patient's teeth. JA2034. Over time when worn, the aligner gently moves the patient's teeth in line with the aligner's cavities. JA2034; JA92972. Once the teeth are generally lined up with that aligner's cavities, the patient moves to a subsequent aligner, which repositions the teeth closer to their ultimate position. JA2034. That process is repeated until the final desired arrangement is achieved. JA2034.

Because each patient's teeth are unique, each aligner must be custom-designed, and configuration for each treatment stage is critical. JA2034; JA95995. By generating and obtaining data determining the positioning of a patient's teeth, a complex three-dimensional digital models of each particular configuration can be created. JA2028-30; JA95995. These digital data sets are then used to mold the

dental aligners. JA2030-31; JA95996.

The Invisalign System, developed by Align over many years and at great expense and effort, represents a vast improvement over conventional methods of treating teeth misalignment. JA2032-34. The innovations embodied in the Invisalign System are protected by numerous United States and foreign patents and trade secrets, including the patents-in-suit. JA2033; JA1841-42.

B. Align's 2006 Litigation Against OrthoClear.

In 2005, Align's founder and former Chief Executive Officer, Mohammad Chisti, founded OrthoClear — a company designed to compete with Align, using former Align employees in Pakistan to design and make clear aligners. JA2022 ¶¶ 9-10. Believing its patents were being infringed, Align filed a complaint with the Commission in January 2006, and the Commission instituted an investigation against OrthoClear. JA199.8; JA32; *see also Certain Incremental Dental Positioning Adjustment Appliances*, ITC Inv. No. 337-TA-562, Notice of Investigation, 71 Fed. Reg. 7,995 (Feb. 15, 2006).

Ultimately, OrthoClear agreed to enter into a settlement with Align. JA199.8; JA32. On November 13, 2006, the Commission entered the Consent Order required by the terms of the settlement agreement and terminated the investigation. JA199.8-199.9; JA32-33; *Certain Incremental Dental Positioning Adjustment Appliances*, ITC Inv. No. 337-TA-562, Notice of Commission

Decision Not To Review the Administrative Law Judge's Initial Determination
Granting a Joint Motion To Terminate the Investigation Based on a Consent Order,
2006 WL 3462199 (U.S.I.T.C. Nov. 13, 2006).

The Consent Order contained successor and aiding-and-abetting provisions that extended the order's prohibitions beyond OrthoClear. *See JA199.9; JA33.* In March 2012, Align initiated an enforcement proceeding against ClearCorrect and various individual respondents (all of whom were former OrthoClear management) for the violation of the successor and aiding-and-abetting provisions of the Consent Order. JA199.9-199.10; JA33-34. Align alleged that ClearCorrect and the individual respondents violated the Consent Order by importing into the United States, offering for sale, or selling for importation digital data sets used to mold dental aligners in the United States, and that such acts induced and/or contributed to the infringement of Align's patents. JA199.10; JA34. Two days before the evidentiary hearing was to begin, the Commission terminated the investigation, finding no violation based on its conclusion that the Consent Order did not cover electronic transmissions. JA199.10; JA34. This Court vacated that decision, and remanded the case to the Commission. *See Align Technology, Inc. v. ITC*, Nos. 2013-1240, -1363, 2014 WL 3537066 (Fed. Cir. July 18, 2014). Align's enforcement complaint is currently pending before the Commission in Investigation No. 337-TA-562.

C. ClearCorrect and Its Infringing Technology.

On March 8, 2007, shortly after OrthoClear ceased its operations, one of OrthoClear's customers, Dr. Willis Pumphrey, founded a company named ClearCorrect Systems, LLC — a predecessor company of Intervenor ClearCorrect USA. JA2134-37 ("ClearCorrect: Competing at the Cutting Edge"); JA2139-41 ("Necessity Knows the Law — The Next Stage Bootstrapper").

From its inception, ClearCorrect USA made no pretense that its process was materially different from Align's. Rather, ClearCorrect USA announced that it found a legal "opening" "to continue servicing [its] patients" with clear aligner therapy. JA2134-37; JA2139-41. To this end, ClearCorrect USA began working in tandem with ClearCorrect Pakistan. Instead of having a single entity handle all phases of designing and forming dental aligners, ClearCorrect USA and ClearCorrect Pakistan split up the tasks. ClearCorrect Pakistan creates the digital data sets used to create the molds on which the aligners are formed, and transmits these data sets to ClearCorrect USA. JA199.21; JA45 JA199.23-199.24; JA47-48; JA1091-92; JA719-23. ClearCorrect USA then uses the digital data sets to create the molds necessary to manufacture and sell aligners in the United States. JA199.21-199.22; JA45-46; JA199.24; JA48.

Specifically, ClearCorrect USA first "scan[s] stone models of a patient's dental impressions, which represent the patient's initial tooth arrangement."

JA199.22; JA47; JA1542. ClearCorrect USA then uploads the 3D digital scan to a server for ClearCorrect Pakistan to access. JA199.23; JA47; JA944. Upon receipt, ClearCorrect Pakistan imports the data into FreeForm, a 3D modeling software program, to prepare the initial digital data set. JA199.23-24; JA47; JA944. Using this modeling software, ClearCorrect sections the initial digital data sets representing the initial position of teeth for the upper and lower jaws into 16 separate teeth, and manipulates the tooth positions on the computer model to create proposed tooth positions. JA199.23; JA47; JA730. Once ClearCorrect Pakistan creates a model of the final position of the teeth, which is the proposed “treatment setup,” ClearCorrect Pakistan transmits this “treatment setup” to ClearCorrect USA by uploading the setup to the ClearCorrect USA server. JA199.23; JA47; JA719. ClearCorrect USA then sends the “treatment setup” to the treating professional for approval. JA199.23; JA47; JA719.

If the dentist approves the intended final teeth positioning, ClearCorrect Pakistan proceeds to the “stepping process,” which consists of creating, with the same modeling software, steps, or intermediate tooth positions, that incrementally move the teeth from their initial position to the final position. JA199.24; JA48; JA719. These created steps make up ClearCorrect’s digital data sets. ClearCorrect Pakistan then “electronically transmits the digital data sets to ClearCorrect USA by uploading them onto the ClearCorrect USA server.” JA199.24; JA48.

ClearCorrect USA uploads the data sets into a software program which is used to fabricate physical models of the incremental teeth positions. JA199.24; JA48; JA1091-92. ClearCorrect USA then molds dental aligners by thermoplastic molding over a physical model of the teeth.” JA199.21-199.22; *see also* JA199.24.

D. The Commission’s Investigation and the Patents at Issue.

On March 1, 2012, Align filed its complaint against Intervenors with the Commission. JA2012.¹ The Commission instituted the investigation against Intervenors on April 5, 2012. JA199.5; JA29; *see also Certain Digital Models, Notice of Investigation*, 77 Fed. Reg. 20648-49 (Apr. 5, 2012). In its complaint, Align alleged that Intervenors violated section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, by importing into the United States, selling for importation, and selling within the United States after importation digital models, digital data, and treatment plans for use in making dental appliances in the United States, and that such acts infringed various patents held by Align. JA199.5-199.6; JA29-30; JA24653 ¶¶ 1-4.

Specifically, Align asserted that Intervenors infringed certain claims of the following patents: U.S. Patent Nos. 6,217,325 (“the ’325 patent”); 6,722,880 (“the ’880 patent”); 8,070,487 (“the ’487 patent”); 6,471,511 (“the ’511 patent”); 6,626,666 (“the ’666 patent”); 6,705,863 (“the ’863 patent”); and 7,134,874 (“the

¹ Align filed a corrected complaint on March 22, 2012. *See* JA24642-43.

'874 patent") (collectively "patents-in-suit"). JA199.5-6; JA29-30; JA24679-84.

The asserted patents are generally directed toward a system for repositioning teeth consisting of individual aligners that are configured to be placed successively on the patient's teeth and to reposition the teeth incrementally to a desired final arrangement. JA199.11; JA3025 (Abstract).

The asserted claims of the '325 patent are directed to, among other things, methods for fabricating dental incremental position adjustment appliances "using digital data sets representing an initial tooth arrangement, a final tooth arrangement, and a series of intermediate digital data sets representing the tooth arrangements progressing from the initial to the final arrangement." JA199.12; JA36; JA2931 (Col. 16:19-34).

The '880 patent teaches methods of using digital data sets representing both the initial and successive tooth arrangements to fabricate aligners. JA199.13; JA37; JA3057 (Col. 22:12-29). Similarly, the claims of the '666 patent are directed to a method of producing a "plurality of digital data sets" by "moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set." JA199.16-199.17; JA40-41; JA2978 (Col. 15:27-48).

The asserted claims of the '487 patent are directed to a method of planning a orthodontic treatment by producing digital data sets and orthodontic treatment plans for repositioning a patient's teeth using incremental tooth repositioning

appliances. JA199.14-199.15; JA38-39; JA3128-29 (Col. 10:61-11:44). Similarly, the asserted claims of the '874 patent are directed to methods for "creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions." JA199.18-199.19; JA42-43; JA3107 (Col. 32:37-56).

The '511 patent relates to computer-implemented methods of creating orthodontic treatment plans. In the inventions claimed in the '511 patent, the treatment path of each tooth is segmented and the tooth's motion in each segment is evaluated to stay within limits of acceptable linear and rotational translation, with aligners for each treatment segment being generated afterwards. JA199.15-199.16; JA39-40; JA2951 (Abstract); JA2958 (Col. 11:4-20).

The asserted claims of the '863 patent disclose a method of "producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment." JA199.17-199.18; JA41-42; JA3021 (Ex Parte Reexam Cert. Col. 1:57-2:4).

The asserted claims of the seven patents-in-suit share common characteristics, and in the proceeding below Align placed them into four general groups for the purpose of analyzing whether ClearCorrect's acts violated the prohibitions of section 337. JA199.19-199.20; JA43-44. The Commission followed this nomenclature in its analysis.

Group I (claims 21 and 30 of the '325 patent and claim 1 of the '880 patent)

consists of claims directed to a method of forming dental appliances using digital data sets. JA199.20; JA44. Align alleged, and the ALJ and Commission agreed, that Intervenors violated section 337(a)(1)(B)(i) where ClearCorrect USA performs each claimed step in the United States and thus directly infringes under 35 U.S.C. § 271(a), using imported digital data created by ClearCorrect Pakistan, where the imported data contributorily infringes under 35 U.S.C. § 271(c). This violation finding is correct and is not part of Align's appeal.

Group II (claims 31 and 32 of the '325 patent; claims 1 and 4-8 of the '863 patent; claims 1, 3, 7 and 9 of the '666 patent; and claims 1, 3 and 5 of the '487 patent) includes claims directed to methods of producing digital data sets. JA199.20; JA44. Align alleged, and the ALJ and Commission agreed, that Intervenors violate section 337(a)(1)(B)(ii) when they import, sell for importation, or sell after importation, digital data sets made according to the asserted claims. This violation finding is likewise correct and is not part of Align's appeal.

Group III (claims 7-9 of the '487 patent) consists of claims directed to treatment plans (*i.e.*, a series of digital data sets). JA199.20; JA44. Align alleged that Intervenors violate section 337(a)(1)(B)(i) where Respondents import, sell for importation, or sell after importation, digital data sets that meet the limitations of these claims under 35 U.S.C. § 271(a). The ALJ and the Commission did not find a violation of these claims, and this is the basis of the first issue Align presents in

this appeal, as discussed below. *See infra* at 28-32.

Group IV (claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, 39 of the '325 patent; claims 1 and 3 of the '880 patent; claims 1 of the '511 patent; and claims 1, 2, 38, 39, 41, and 62 of the '874 patent) contains claims directed to methods of manipulating digital data sets and using them to create dental appliances. JA199.20; JA44.² Align alleged that Intervenors violate section 337(a)(1)(B)(i) with regard to these claims when they import, sell for importation, or sell after importation, digital data sets made by ClearCorrect Pakistan according to the steps of various claims, and ClearCorrect USA then creates aligners based on the digital data. The imported digital data sets contributorily infringe under 35 U.S.C. § 271(c), and the ultimate sale, offer for sale, or use of the aligners by ClearCorrect USA is a direct infringement under 35 U.S.C. § 271(g). While the ALJ found a violation of the Group IV claims, the Commission declined to find a violation. This ruling by the Commission is the basis of the second issue presented in Align's appeal. *See infra* at 32-52.

1. The ALJ's Initial Determination.

On May 6, 2013, the ALJ issued an Initial Determination ("ID"), finding a violation of section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, the '863 patent, and the '874 patent. JA199.6; JA30;

² Group IV includes some asserted claims that were also placed in Groups I and II. JA199.20; JA44.

JA1883.³ As an initial matter, the ALJ addressed the threshold question of whether ClearCorrect's digital data sets constitute "articles" within the meaning of section 337 of the Tariff Act, 19 U.S.C. § 1337. The ALJ concluded, based on the statutory language and the Commission precedent, that Intervenors' electronic transmission of digital data sets into the United States constitutes "importation" of "articles" under section 337. JA199.26-199.27; JA50-51; JA1087-90; JA263-66.

The ALJ then found a violation with respect to the Group I patent claims, concluding, *inter alia*, that ClearCorrect Pakistan contributorily infringes these claims when it transmits the digital data sets to ClearCorrect USA. JA199.73-199.75; JA97-98; JA1619; JA1659. The ALJ also found that Intervenors violated section 337 with respect to the Group II claims by importing into the United States digital data sets made abroad by the method patented under these claims. JA199.94-199.95; JA118; JA1620; JA1694; JA1740; JA1802.⁴ The ALJ likewise found a violation with respect to the Group IV claims, concluding, *inter alia*, that ClearCorrect USA and ClearCorrect Pakistan acted in concert to practice these product-by-process claims. JA199.109-199.110; JA132-33; JA1620-21; JA1662-63; JA1709; JA1828-29. The ALJ concluded that such conduct violated two

³ Previously, on January 14, 2013, the ALJ issued an order finding that ClearCorrect had waived any estoppel defense, including defenses based on implied license or patent exhaustion. JA199.6; JA30; JA59808, 59830-33.

⁴ The ALJ concluded, however, that Align did not satisfy the technical prong of the domestic industry requirement as to the '666 patent, JA1857-58 — an erroneous finding that the Commission corrected, JA199.144-199.147; JA168-71.

separate provisions of section 337 — 19 U.S.C. § 1337(a)(1)(B)(i) (combined with 35 U.S.C. § 271(g)) and 19 U.S.C. § 1337(a)(1)(B)(ii). JA199.110; JA134; JA1502.

The ALJ found no violation with respect to Group III claims. JA199.105; JA128-29. The ALJ acknowledged that the intermediate digital data sets produced by ClearCorrect Pakistan met each and every claim limitation when stored on a ClearCorrect USA or ClearCorrect Pakistan computer or server, and that the data sets were transmitted from between these computers or servers. JA1686-89. The ALJ concluded, however, that the data sets did not reside on a “storage media” at the precise moment of electronic transmission, and therefore did not meet that claim limitation “at the time of importation.” JA1689.

The ALJ recommended the issuance of cease-and-desist orders directed to ClearCorrect USA and ClearCorrect Pakistan, prohibiting the importation of the accused digital models, digital data sets, and treatment plans. JA199.6; JA30; JA199.148; JA171-72; JA1872.

2. The Commission’s Determination.

The Commission decided to review the ALJ’s Initial Determination, and solicited extensive briefing from the parties and the public on the issues involved. JA199.7; JA31; JA234-38; JA97739-42. On April 3, 2014, the Commission issued its determination and an accompanying opinion. JA214; *Certain Digital Models*,

Comm'n Determination, 79 Fed. Reg. 19640-41 (Apr. 9, 2014).

The Commission agreed with the ALJ that the accused products are “articles” within the meaning of section 337 and that electronic transmission of these articles into the United States constitutes importation under that statute. JA214; JA199.25-199.26; JA49-50; JA199.38; JA199.59. The Commission carefully reviewed the plain language of the statute; contemporaneous dictionary definitions; congressional purpose in enacting section 337; legislative history; relevant case law, including the decisions of this Court and the Supreme Court; the Commission’s prior decisions; the position of other federal agencies with responsibilities over international trade; and the extensive arguments made in the public comments solicited by the Commission. JA199.25-199.59; JA49-83. After this detailed analysis, the Commission concluded that the statutory phrase “importation ... of articles” in section 337 should be construed to include electronic transmission of digital data because the “digital data sets at issue in this investigation are true articles of international commerce that are imported into the United States and their inclusion within the purview of section 337 would effectuate the central purpose of the statute.” JA199.59; JA83.⁵

After addressing certain claim construction issues, JA199.59-199.71, the Commission turned to infringement and found a violation with respect to Group I

⁵ Commissioner Johanson dissented from the Commission’s interpretation of Section 337. JA199.158-199.173; JA182-197.

and Group II patent claims. Specifically, the Commission found that ClearCorrect's importation, sale for importation, and sale after importation of the accused digital models, digital data sets, and treatment plans infringed the following patent claims held by Align: (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. JA214; JA199.73-199.104; JA97-128. As a remedy for the section 337 violation, the Commission issued cease-and-desist orders prohibiting Intervenors from importing the infringing products and from engaging in associated marketing, selling, advertising, and solicitation activity, with an exemption for the treatment of existing patients in the United States. JA214; JA215-32.⁶

The Commission, however, found no violation with respect to Group III claims and claims included solely in Group IV. As to Group III (claims 7-9 of the '487 patent), the Commission affirmed the ALJ's finding that, although the accused digital treatment plans created by ClearCorrect Pakistan were stored on a storage medium (namely, the ClearCorrect USA computers or servers) upon being transmitted to the United States, these digital data sets did not reside on "storage

⁶ Subsequent to the issuance of the Commission's cease-and-desist orders, Intervenors requested a clarification and a modification of the Commission's orders, arguing that the orders could be read as extending to "wholly domestic conduct." JA101541-42. The Commission clarified that its cease-and-desist orders "proscribe only activities involving imported covered products" and, finding the orders to be clear, declined to modify them. JA101545.

media” during the precise moment of their electronic transmission, and therefore did not meet all the relevant claim limitations at the time of importation.

JA199.105-107; JA130-131; JA1686-1689. Consequently, the Commission concluded that there was no direct infringement of the Group III claims at the time of importation. JA199.107; JA131.

With respect to the Group IV claims (which disclose methods for fabricating dental appliances), the Commission reversed the ALJ’s finding of a section 337 violation. First, the Commission rejected the ALJ’s conclusion that ClearCorrect’s practice of these methods constituted a violation of 19 U.S.C. § 1337(a)(1)(B)(ii), since the last claim step was not performed prior to importation. JA199.117; JA140-41. Second, the Commission rejected the ALJ’s finding of a violation under 19 U.S.C. § 1337(a)(1)(B)(i) (combined with 35 U.S.C. § 271(g)), concluding that infringement under 35 U.S.C. § 271(g) cannot form the basis for a finding of violation of section 337(a)(1)(B)(i). JA199.117-199.118; JA141. In the Commission’s view, section 337(a)(1)(B)(ii) was a “specific provision” addressing importation of articles produced by a patented process, whereas section 337(a)(1)(B)(i) was a “general provision.” JA199.118; JA141. Therefore, the Commission opined, violations of section 337 based on process of manufacture claims should be addressed solely under section 337(a)(1)(B)(ii), and not section 337(a)(1)(B)(i) read in conjunction with 35 U.S.C. § 271(g). JA199.117-199.118;

JA141. In support of this conclusion, the Commission invoked this Court's decision in *Kinik Co. v. ITC*, 362 F.3d 1359 (Fed. Cir. 2004), which held that the statutory defenses to infringement under 35 U.S.C. § 271(g) are not available in section 337(a)(l)(B)(ii) actions before the Commission. JA199.118; JA141-42. Extrapolating from this holding, the Commission concluded Congress intended the entirety of section 271(g) to apply *only* in district courts, and not in Commission proceedings involving process patents. JA199.118-199.119; JA142.

STANDARD OF REVIEW

This Court reviews the Commission's legal determinations *de novo* and factual determinations for substantial evidence. *Amkor Tech., Inc. v. ITC*, 692 F.3d 1250, 1254 (Fed. Cir. 2012). On interpretations of the Tariff Act, this Court applies the familiar framework of *Chevron USA, Inc. v. NRDC*, 467 U.S. 837 (1984): "When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If the statute is ambiguous, this Court defers to the agency's interpretation only if it is reasonable. *Id.* at 843-44.

SUMMARY OF ARGUMENT

In finding no violation of Align's asserted Group III claims, the Commission adopted an artificially narrow interpretation of 19 U.S.C. § 1337's term "importation" in the context of electronic articles. The Commission held that, because the accused digital data sets were imported into the United States by electronic transmission, they did not reside on a computer readable storage medium "at the time of importation," and therefore did not meet all the asserted claim limitations. The act of importation, however, encompasses the entire process of bringing products into the United States from abroad. For physical products, importation does not end at the moment the goods cross the territorial boundary of the United States (such as its territorial waters); rather, the goods are considered "imported" upon entry into this country and storage in a customs warehouse. Likewise, importation of electronically transmitted articles is complete when they are received by and stored on a server, not when they enter the territorial limits of the United States while in transit.

Here, Intervenors' importation of the accused digital data sets includes not only the precise act of transmission, but also the saving of the data on a computer or server in the United States. At the time importation via electronic transmission is complete, Intervenors' digital data sets reside on computer-readable storage media, and therefore meet the asserted claim limitations and infringe Align's

patents.

The Commission also erred in concluding that 35 U.S.C. § 271(g) does not apply in the Commission proceedings under 19 U.S.C. § 1337. Section 337(a)(1)(B)(i) applies to “articles that … *infringe* a valid and enforceable United States patent” (emphasis added), and under this Court’s precedent, the provisions of the Patent Act determine what constitutes infringement. Section 271(g) made it an act of infringement to “import[] into the United States … a product which is made by a process patented in the United States.” By its very terms, therefore, section 337(a)(1)(B)(i) encompasses within its scope product-by-process infringement under 35 U.S.C. § 271(g). The Commission’s contrary conclusion contravenes fundamental principles of statutory interpretation because it reads out of section 337 one of the modes of direct infringement set forth by Congress.

The Commission’s rationale for excluding 35 U.S.C. § 271(g) from the scope of section 337(a)(1)(B)(i) does not withstand scrutiny. First, the Commission asserted that importation of articles produced by a patented process must be addressed exclusively under a neighboring provision, section 337(a)(1)(B)(ii), because that provision deals specifically with process patents. Section 337(a)(1)(B)(ii), however, is not the more specific provision compared to section 337(a)(1)(B)(i). As the Supreme Court explained, for the general/specific statutory construction canon to apply, the general provision in question must be

“‘broad enough to include’” the specific provision within its scope. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (citation omitted). Section 337(a)(1)(B)(i) does not encompass section 337(a)(1)(B)(ii) within its scope. Rather, they are complementary provisions. While section 337(a)(1)(B)(i) prohibits importation of articles that “infringe,” the plain terms of section 337(a)(1)(B)(ii) do not require an act of infringement. Section 337(a)(1)(B)(ii) was specifically enacted by Congress to cover extraterritorial use of patented processes, which was not protected by the substantive patent laws at the time and therefore (under a decision by this Court’s predecessor court) not actionable pursuant to section 337(a)(1)(B)(i). The addition of 35 U.S.C. § 271(g) as a basis of infringement in 1988 does not change this analysis, as section 337(a)(1)(B)(ii) remains of a different scope than section 337(a)(1)(B)(i) read in conjunction with 35 U.S.C. § 271(g). Section 337(a)(1)(B)(ii) covers both articles that were “made” (as in section 271(g)), and articles that were “produced, processed, or mined.” By its plain terms, section 337(a)(1)(B)(ii) would extend to acts — such as extracting minerals through the use of a patented process — that would not necessarily fit within a combination of section 337(a)(1)(B)(i) and section § 271(g).

The Commission’s reliance on this Court’s decision in *Kinik Co. v. ITC*, 362 F.3d 1359 (Fed. Cir. 2004), is similarly misplaced. *Kinik* does not mandate the

conclusion that section 271(g) applies solely in district court actions, and not in the Commission proceedings. The *Kinik* court held only that that section 271(g)'s *defenses* are not available in section 337(a)(1)(B)(ii) actions, and based that conclusion on 35 U.S.C. § 271(g)'s express reservation that such defenses apply solely "for purposes of this title." But section 271(g)'s limitation of prescribed statutory defenses to actions brought under Title 35 does not mean the *offensive* use of section 271(g)'s other provisions should be similarly limited. Indeed, the definitional sentence of section 271(g), which provides that importation of a product made by a patented process shall be an act of infringement, contains no such reservation. Congress's use of the limiting term "this title" in other clauses of section 271(g), but not in the definitional clause, indicates that Congress *did not intend* to limit its definition of infringement under this provision solely for Title 35 actions. *Russello v. United States*, 464 U.S. 16, 23 (1983). The Commission's construction of section 337(a)(1)(B)(i) would unnecessarily impair the ability of patent-holders to address joint global business operations designed specifically to avoid infringement liability. This Court should correct the Commission's erroneous interpretation and reaffirm that section 337(a)(1)(B)(i) authorizes the Commission to reach all acts that constitute "importation ... of articles that infringe" under the provisions of the Patent Act.

ARGUMENT

I. THE COMMISSION ERRED IN CONCLUDING THAT THE ACCUSED DIGITAL DATA SETS WERE NOT STORED ON A “COMPUTER READABLE STORAGE MEDIA” DURING IMPORTATION.

The Commission has accurately observed, in conformity with the Supreme Court precedent, that importation “consists in bringing an article into a country from the outside … regardless of the mode by which it is effected,” JA199.45 (quoting *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923)); JA68-69, and correctly held that electronic transmission of digital data sets into the United States constitutes importation under 19 U.S.C. § 1337, *see* JA199.59; JA83. The Commission, however, adopted an artificially narrow interpretation of the term “importation” in the context of electronic articles. The Commission’s erroneous interpretation contravenes the meaning of this statutory term, which does not admit of ambiguity that leaves interpretive room for the agency. The Commission’s interpretation, therefore, fails at the first step of *Chevron*. But even if the term “importation” were deemed to be ambiguous, the Commission’s interpretation is not a reasonable construction of the statute.

Align’s Group III claims are directed to treatment plans, and include a recitation that the treatment plan “resid[es] on a computer readable storage media.” JA199.105; JA128; *supra* at 16-17. The Commission, with little analysis, affirmed the ALJ’s cursory finding that, because these digital data sets were “imported by

being transmitted *electronically*, not on a computer readable storage media,” they did not meet this limitation “at the time of importation.” JA1689 (emphasis added); JA199.106-199.107 (adopting the ALJ’s findings); JA130-31.

The analysis of a violation of the “importation” prong of section 337(a)(1)(B) — and of whether the accused article meets the asserted claim limitations during importation — should not be limited to the status of the article while being transported in a particular mode (*e.g.*, *via* boat, plane, or the internet). Rather, as the Supreme Court explained, the term “importation” is concerned with whether the article has been brought into the United States from abroad, “*regardless of the mode in which [the actual bringing] is effected.*” *Cunard S.S. Co.*, 262 U.S. at 122 (emphasis added). The term “importation,” according to a dictionary definition contemporaneous with section 337’s enactment, means an “[a]ct or practice of importing, or bringing in, esp. of goods or merchandise from abroad into a country or state.” *Webster’s New International Dictionary of the English Language* 1081 (1927) (first definition of “importation”) (available at JA97357); *see also Webster’s New International Dictionary of the English Language* 1081 (1927) (“import”: “2. To bring in from a foreign or external source; to introduce from without; esp., to bring (wares or merchandise) into a place or country from a foreign country in the transaction of commerce.”) (available at JA97357). This meaning has remained consistent over time. *See*,

e.g., *Webster's New World Dictionary* 678 (3d college ed. 1988) ("1(a) to bring in from the outside; introduce (b) to bring (goods) from another country or countries, esp. for purposes of sale.") (available at JA98218).

Accordingly, courts view the act of importation as encompassing the entire process of bringing products into the United States, with the goal of effectuating an actual "bringing in" of the product into the country from abroad. *See, e.g., United States v. Commodities Export Co.*, 733 F. Supp. 109, 112 (Ct. Int'l Trade 1990) ("[I]mportation, consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode in which it is effected.") (citing *Cunard*, 262 U.S. at 122); *United States v. Field & Co.*, 14 Cust. App. 406, 407 (Ct. Cust. App. 1927) ("Importation ... consists in bringing an article into a country from the outside. If there be an actual bringing in, it is importation regardless of the mode in which it is effected."") (quoting *Cunard*, 262 U.S. at 122).

Similarly, U.S. Customs — the federal agency charged with administering trade laws — defines "importation" as "the *arrival* of [goods] in the United States." USITC Pub. 2812, Sept. 1994, Letter of Department of the Treasury, U.S. Customs Service, Office of Chief Counsel, June 22, 1994, at 4 (emphasis added).

Therefore, when analyzing, for purposes of ascertaining a section 337(a)(1)(B) violation, whether an article imported into the United States meets the

asserted claim limitations, the focus should be on the status of the article once it arrives in the United States. This Court has held, when construing the term “importation of merchandise” in a jurisdictional statute of the Court of International Trade, 28 U.S.C. § 1582, that physical goods “are ‘imported’ upon entry into this country and storage in a bonded warehouse.” *Commodities Export*, 972 F.2d at 1269 (citing, *inter alia*, *Cunard S.S. Co.*, 262 U.S. at 122). Importation does not end at the moment the goods cross the territorial boundaries of the United States (which are the territorial waters). Likewise, importation of electronically transmitted articles is complete when they are received by and stored on a server, not when they enter the territorial limits of the United States while in transit.

Here, as the Commission found, Intervenors’ digital data sets are stored on ClearCorrect Pakistan’s computers or servers, and are then electronically transmitted to ClearCorrect USA’s computers or servers located in the United States. JA199.23-24; JA47-49; Ja199.105; JA128. In the course of importation, the digital data sets are received by, and stored on, ClearCorrect USA’s computers or servers. JA199.23-24; JA47-49; JA199.105; JA128. Under the settled interpretation of what constitutes “importation,” ClearCorrect’s act of importation includes the entire process of importation — not only the precise act of transmission, but also the saving of the data on a computer or server in the United States. There is no plausible rationale for the Commission’s unwarrantedly narrow

focus solely on the time when the electronic data sets are momentarily en route between a server outside the United States and a server inside the United States — literally mere seconds (or less) in view of the speed of electronic transmission. In fact, it is impossible to “bring[]” digital data sets into the United States electronically without saving them on a computer or server at the end of the transmission process.

There is no dispute that, at the time importation (via electronic transmission) is complete, the digital treatment plans reside on computer-readable storage media, and therefore meet the asserted claim limitations. JA199.23-24; JA47-49; JA199.105; JA128. The Commission’s finding of no infringement with respect to the Group III claims should therefore be reversed.

II. THE COMMISSION ERRED IN CONCLUDING THAT INFRINGEMENT UNDER 35 U.S.C. § 271(g) CANNOT FORM THE BASIS OF A SECTION 337 VIOLATION.

A. Section 337(a)(1)(B)(i)’s Prohibition of “Importation ... of Articles that Infringe” Extends to All Acts of Infringement Specified in 35 U.S.C. § 271.

The Commission’s conclusion that 35 U.S.C. § 271(g) “does not apply” in section 337 proceedings before the Commission, JA199.118; JA142, is based on an erroneous construction of the statutory scheme. This plain language of the statutory provisions at issue — 19 U.S.C. § 1337(a)(1)(B)(i)-(ii) and 35 U.S.C. § 271(g) — when interpreted with the aid of the “traditional tools of statutory

construction,” including the “statute’s text, structure, and legislative history, and ... the relevant canons of interpretation,” *Delverde, SrL v. United States*, 202 F.3d 1360, 1363 (Fed. Cir. 2000), is dispositive, and mandates a conclusion that section 271(g) is available in Commission proceedings alleging a violation based on the importation of articles produced by a patented process.

Section 337(a)(1)(B) makes unlawful, and authorizes remedial action by the Commission with respect to:

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of *articles that* —

(i) *infringe a valid and enforceable United States patent* or a valid and enforceable United States copyright registered under title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B) (emphasis added).

As the Commission has acknowledged, “the word ‘infringe’ in section 337 derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement. *Certain Electronic Devices*, Inv. No. 337-TA-724, Comm’n Determination, 2012 WL 3246515, at *9 (U.S.I.T.C. Dec. 21, 2011) (citing *Tianrui Group Co. v. ITC*, 661 F.3d 1322, 1333 (Fed. Cir. 2011)); see also *Texas Instruments, Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1330 (Fed. Cir. 2000) (“In

section 337 proceedings relevant to patent infringement, the ITC follows Title 35 of the United States Code and the case law of this court.”) (citing 19 U.S.C. § 1337(c)). As the Commission recognized, “the term ‘infringement’ embraces any direct, contributory and induced infringement.”” *Certain Hardware Logic*, Inv. No. 337-TA-383, Comm’n Opinion on Remedy, the Public Interest, and Bonding, 1998 WL 307240, at *10 (U.S.I.T.C. Mar. 1998) (citation omitted); *see also Certain GPS Chips*, Inv. No. 337-TA-596, Comm’n Determination, 2010 WL 1502175, at *32 (U.S.I.T.C. Mar. 2010) (“The unfair acts covered under Section 337 include ‘*all forms of infringement*, including direct, contributory, and induced infringement.’”) (discussing requirements of 35 U.S.C. § 271(a)-(c)) (citation omitted) (emphasis added); *Spansion, Inc. v. ITC*, 629 F.3d 1331, 1337, 1343 (Fed. Cir. 2010) (affirming the Commission finding of both direct and contributory infringement under 35 U.S.C. § 271(c)); *Young Eng’rs, Inc. v. ITC*, 721 F.2d 1305, 1308-09 (Fed. Cir. 1983) (affirming the Commission finding that respondents had infringed directly, had contributorily infringed, and had induced infringement).

Section 271(g) was enacted as “part of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 … [and] was intended to provide ‘patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their

patented process.”” *Kinik Co. v. ITC*, 362 F.3d 1359, 1362 (Fed. Cir. 2004) (quoting S. Rep. No. 100-83, at 29 (1987)). Specifically, section 271(g) provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. ... A product which is made by a patented process will, for purposes of this title, not be considered to be so made after —

- (1) it is materially changed by subsequent processes; or
- (2) it becomes a trivial and nonessential component of another product

35 U.S.C. § 271(g) (emphasis added).

As this Court observed, section 271(g) extends the liability for direct infringement, which was previously defined by 35 U.S.C. § 271(a), to instances “when the product of a patented process is used in, or imported into, the United States.” *Zoltek Corp. v. United States*, 672 F.3d 1309, 1327 (Fed. Cir. 2012); *see also Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1378 n.1 (Fed. Cir. 2011) (finding it unnecessary to address appellant’s “arguments that [appellee] is liable for direct infringement under 35 U.S.C. § 271(g)”). Numerous district courts have similarly treated 19 U.S.C. § 271(g) as imposing liability for direct infringement with respect to product-by-process claims. *See, e.g., W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 874 F. Supp. 2d 526, 545-46 (E.D. Va.

2012) (addressing “Direct Infringement under Section 271(g)”), *aff’d*, 530 F. App’x 939 (Fed. Cir. 2013); *Designing Health, Inc. v. Erasmus*, No. 98-4758, 2002 WL 34536686, at *9 (C.D. Cal. Feb. 26, 2002) (“Within the context of method patent claims, 35 U.S.C. § 271(g) defines a form of direct infringement.”) (citing *Avery Dennison Corp. v. UCB Films, PLC*, No. 95-C-6351, 1997 WL 665795, at *2 (N.D. Ill. Oct. 20, 1997)).

By its very terms, therefore, 19 U.S.C. § 1337(a)(1)(B)(i) encompasses within its scope product-by-process infringement under 35 U.S.C. § 271(g). Section 337(a)(1)(B)(i) applies to “*articles that ... infringe a valid and enforceable United States patent,*” 19 U.S.C. § 1337(a)(1)(B)(i) (emphasis added), and section 271(g) broadened the definition of patent infringement to include acts of “import[ing] into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States,” 35 U.S.C. § 271(g). “[T]he words of a statute must be read ... with a view to their place in the overall statutory scheme,” *Util. Air Regulatory Group v. EPA.*, 134 S. Ct. 2427, 2441 (2014) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)) (internal quotation marks omitted), and so as “to give effect, if possible, to every clause and word of a statute,” *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (internal quotation marks omitted). See also 2A Norman J. Singer & J.D. Shambie Singer, *Statutes and Statutory Construction* § 46:5, at 202-

05 (7th ed. 2007) (hereinafter, “*Sutherland on Statutory Construction*”) (a court should “not only consider the particular statute in question, but also the entire legislative scheme of which it is a part”); *id.* § 46:5 at 206-08 (“a statutory subsection may not be considered in a vacuum, but must be considered in reference to the statute as a whole and in reference to statutes dealing with the same general subject matter”); *id.* § 46:6, at 230-42 (“[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant”).

The Commission’s conclusion that “§ 271(g) does not apply to Section 337,” JA199.119; JA142, contravenes these fundamental principles of statutory construction, because it reads out of section 337 one of the modes of direct infringement set forth by Congress in the Patent Act and referenced in section 337(a)(1)(B)(i). As the Supreme Court instructed, “[i]t is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.” *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (internal quotation marks omitted); *see also* 2A *Sutherland on Statutory Construction* § 46:6, at 244-47 (“No clause, sentence or word shall be construed as superfluous, void or insignificant if a construction can be found which will give force to and preserve all the words of the statute.”).

Under the Commission's contrived interpretation of section 337(a)(1)(B), the product-by-process infringement defined by 35 U.S.C. § 271(g) is *the only* mode of infringement under the Patent Act that is not incorporated by reference into, and the *only* subsection of 35 U.S.C. § 271 not otherwise relevant to, section 337 violation analysis. Regarding infringement findings, both this Court's and the Commission's section 337 cases are premised not only on the original provision of section 271 — 35 U.S.C. § 271(a), which defines traditional direct infringement — but also on the additional infringement provisions subsequently added by Congress to cover infringement by inducement and contribution, 35 U.S.C. § 271(b) and (c), respectively. *Supra* at 33-34.

Moreover, the Commission has routinely adopted or integrated the other provisions of 35 U.S.C. § 271 when determining infringement and violations in section 337 cases. For example, the Commission has applied Section 271(d)'s provisions when analyzing misuse defenses, Section 271(e)(1)'s safe harbor provisions, and Section 271(f)'s language when determining violations. *See, e.g., Certain Flash Memory Controllers, Drivers, Memory Cards, and Media Players*, Inv. No. 337-TA-619, 2010 ITC LEXIS 808, at *186 (U.S.I.T.C. Apr. 10, 2009) (analyzing section 271(d) in the context of its proceeding); *Certain Recordable Compact Discs and Rewritable Compact Discs*, Inv. No. 337-TA-474, 2004 ITC LEXIS 990, at *7-17 (U.S.I.T.C. Apr. 8, 2004) (same); *Certain Flooring Products*,

Inv. No. 337-TA-443, 2002 ITC LEXIS 241, *240-241 (U.S.I.T.C. May 1, 2002) (same); *Amgen, Inc. v. ITC*, 565 F.3d 846, 848 (Fed. Cir. 2009) (holding that section 271(e)'s safe harbor applies in section 337 proceedings relating to both process and product patents); *Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568 2006 ITC LEXIS 578, at *3 (U.S.I.T.C. Aug. 31, 2006) (finding no violation of section 337 based on the section 271(e) safe harbor); *Certain Bath Accessories and Component Parts Thereof*, Inv. No. 337-TA-306, 1990 ITC LEXIS 88, at *4 (U.S.I.T.C. Mar. 9, 1980) (instituting investigation into allegations of inducement to infringe under section 271(f)(1)). There is no rationale for treating section 271(g) as the ugly duckling of section 271. Nor, as explained below, is there any indication that, in enacting section 271(g), Congress intended to exclude that mode of infringement from the ambit of section 337. *Infra* at 51-52.

B. The Commission's Reliance on the General/Specific Canon Is Misplaced Because Section 337(a)(1)(B)(ii) Is Not More Specific than Section 337(a)(1)(B)(i).

The Commission gave two reasons for finding section 271(g) inapplicable in section 337 proceedings. First, the Commission opined that because “Section 337(a)(1)(B)(ii) ... specifically defines violations of Section 337 based on the importation of articles produced by a patented process,...Section 337(a)(1)(B)(ii) is a special provision which governs over the general provision of Section

337(a)(1)(B)(i).” JA199.117-199.118; JA141. Invoking the “well-established canon of statutory construction that a specific provision governs over a general provision,” the Commission asserted that “violations of Section 337 premised on the importation (or sale after importation) of articles produced by a patented process should be analyzed under Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i).” JA199.117-199.118 (citing *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2068 (2012), and *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)); JA141.

The Commission misapplied the general/specific interpretive canon. As an initial matter, as the Supreme Court noted, this canon is “most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission.” *RadLAX*, 132 S. Ct. at 2071. In such circumstances, “[t]o eliminate the contradiction, the specific provision is construed as an exception to the general one.” *Id.* (citing *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974)). There is no such contradiction between the two subsections of section 337(a)(1)(B); both prohibit the importation of products made by patented processes, and so are complementary.

The canon can also apply to statutes where “a general authorization and a more limited, specific authorization exist side-by-side”; in those situations, “the canon avoids not contradiction but the superfluity of a specific provision that is

swallowed by the general one, ‘violat[ing] the cardinal rule that, if possible, effect shall be given to every clause and part of a statute.’” *RadLAX*, 132 S. Ct. at 2071 (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)). The general/specific canon therefore ensures that “[t]he terms of the specific authorization [are] complied with.” *RadLAX*, 132 S. Ct. at 2071.

Here, however, section 337(a)(1)(B)(ii) is not the more specific provision compared to section 337(a)(1)(B)(i). As the Supreme Court explained, for the general/specific canon to apply, the general provision in question must encompass within its scope the more specific provision. Only if the language of the general provision is “‘broad enough to include’” the specific provision will the general provision “‘not be held to apply to a matter specifically dealt with in another part of the same enactment.’” *Id.* (quoting *D. Ginsberg & Sons*, 285 U.S. at 208). In this way, both provisions are given operative effect, with the specific provision applying to situations covered within its scope and the more general provision governing matters that are not encompassed by the more specific clause:

“[W]here there is, in the same statute, a particular enactment, and also a *general one*, which, in its most comprehensive sense, would include what is embraced in the former, the particular enactment must be operative, and the general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment. This rules applies whenever an act contains general provisions and also special ones upon a subject, which, standing alone, the general provisions would include.”

RadLAX, 132 S. Ct. at 2071 (quoting *United States v. Chase*, 135 U.S. 255, 260 (1890)) (emphasis added).

Section 337(a)(1)(B)(i) cannot be said to encompass within its scope all the matters addressed in section 337(a)(1)(B)(ii). As an initial matter, while section (a)(1)(B)(i) prohibits importation (and associated sale) of articles that “infringe a valid and enforceable United States patent,” 19 U.S.C. § 1337 (a)(1)(B)(i), section 337(a)(1)(B)(ii), by its plain terms, does not require an act of infringement before the Commission can enter an exclusion order, *see id.* § 1337(a)(1)(B)(ii).⁷ This is because section 337(a)(1)(B)(ii) was originally enacted (as former section 19 U.S.C. § 1337a) as a congressional response to the decision by this Court’s predecessor, the Court of Customs and Patent Appeals, in *In re Amtorg Trading Corp.*, 75 F.2d 826 (C.C.P.A. 1935). The *Amtorg* court “held that importing a product made abroad *by patented process* was *not* an unfair trade practice under former section 1337.” *Amgen, Inc. v. ITC*, 902 F.2d 1532, 1538 (Fed. Cir. 1990) (citing *Amtorg*, 75 F.2d at 834) (emphasis in original). In response, Congress overturned the *Amtorg* decision and enacted former section 1337a (later re-codified

⁷ As the legislative history of section 271(g) indicates, “unlike product patents, the use of a patented process outside the United States and a subsequent importation of the product [wa]s not [prior to section 271(g)’s enactment] an act of patent infringement.” H.R. Rep. No. 100-60, at 4-5 (1987). “Instead, a limited, nonpatent form of protection [wa]s afforded under the trade laws (19 U.S.C. § 1337a) enforced by the International Trade Commission.” 133 Cong. Rec. S10275, S10349 (daily ed. July 21, 1987).

as 19 U.S.C. § 1337(a)(1)(B)(ii)) “to prohibit imports made using patented processes.” *Amgen*, 902 F.2d at 1539.

Thus, from its outset, the current section 337(a)(1)(B)(ii) was meant to complement the current section 337(a)(1)(B)(i). Indeed, the former section 1337a, when enacted, expressly stated that, under its terms, “the importation hereafter for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims or any unexpired valid United States letters patent … *shall have the same status for the purposes of section 337 of the Tariff Act of 1930 as the importation of any product or article covered by the claims of any unexpired valid United States letters patent*” — importation that was covered by section 1337(a), section 337(a)(1)(B)(i)’s predecessor. Act of July 2, 1940, ch. 515, 54 Stat. 724 (emphasis added).

The addition of 35 U.S.C. § 271(g) as a basis of infringement in 1988 did not change this analysis. The fact that section 337(a)(1)(B)(ii) is *not* a more specific provision than section 337(a)(1)(B)(i) remains evident from the statutory text, as the scope of section 337(a)(1)(B)(ii) remains different from section 337(a)(1)(B)(i) read in conjunction with 35 U.S.C. § 271(g). As this Court observed, section 337(a)(1)(B)(ii) “covers both articles that were ‘made’ and articles that were ‘produced, processed, or mined.’” *Bayer AG v. Housey Pharms., Inc.*, 340 F.3d 1367, 1374 n.9 (Fed. Cir. 2003). The Court noted that this language

could “suggest[] a broader scope for section 1337 than for section 271(g)” in that regard. *Id.* This observation applies with the same force to section 271(g) as applied in the Commission proceedings by virtue of section 337(a)(1)(B)(i)’s reference to “articles that … infringe a valid and enforceable United States patent.” 19 U.S.C. § 1337(a)(1)(B)(i).

That section 337(a)(1)(B)(ii) could cover acts that would not be encompassed by a combination of section 337(a)(1)(B)(i) and section 271(g) is particularly evident from section 337(a)(1)(B)(ii)’s prohibition on the importation of articles that are “*mined* under, or by means of, a process covered by the claims of a valid and enforceable United States patent.” 19 U.S.C. § 1337(a)(1)(B)(ii) (emphasis added). This provision, by its plain terms, would extend to acts — such as extracting minerals from the ground through the use of a patented process — that would not necessarily fit section § 271(g)’s prohibition on the importation of “a product which is *made* by a process patented in the United States.” 35 U.S.C. § 271(g) (emphasis added).

Thus, section 337(a)(1)(B)(ii) cannot be legitimately said to be “embraced in” section 337(a)(1)(B)(i). *RadLAX*, 132 S. Ct. at 2071 (internal quotation marks omitted). Rather, section 337(a)(1)(B)(ii) is a provision that provides protection against unfair acts of importation alongside section 337(a)(1)(B)(i), even when the latter provision is read (as it should be) to incorporate acts of infringement defined

in 35 U.S.C. § 271(g).

When it added section 271(g) to Title 35 (and simultaneously reenacted prior section 19 U.S.C. § 1337a as the new section 337(a)(1)(B)(ii)), Congress expressly mandated that “[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available … under section 337 of the Tariff Act of 1930.” Pub L. No. 100-418, § 9006(c), 102 Stat. 1107, 1567 (1988). As explained above, *supra* at 33-34, section 337(a)(1)(B)(i), by its plain language, provides relief from “importation … of articles that *infringe* a valid and enforceable United States patent.” 19 U.S.C. § 337(a)(1)(B)(i). It would be contrary to legislative intent to read Congress’ decision to *broaden* the type of acts that constitute patent infringement as implicitly *narrowing* the scope of section 337(a)(1)(B)(i) by excluding a specific type of infringement described in section 271.

In this case, section 337(a)(1)(B)(i) combined with section 271(g) would reach infringing conduct that section 337(a)(1)(B)(ii) alone would not. As the Commission observed (and as Align does not challenge), section 337(a)(1)(B)(ii) would not encompass Intervenors’ activities because “the last claim step” of the Group IV claims — the actual fabrication of dental alliances — “is not performed prior to importation as required by Section 337(a)(1)(B)(ii).” JA199.117; JA140-41. Section 271(g), by contrast, “makes no distinction as to where the steps are performed — it is only concerned with … importation, sale or use of the end

product.” *Avery Dennison Corp.*, 1997 WL 6665795, at *2; *see also Zoltek Corp. v. United States*, 85 Fed. Cl. 409, 420 (Fed. Cl. 2009) (discussing appropriateness of § 271(g) where “part of the claimed process is performed abroad and part of the claimed process is performed in the United States”).⁸ In fact, Congress deliberately crafted section 271(g) to apply to products made by a patented process both within the United States and abroad, in order to comply with United States’ obligations under international trade treaties. *See S. Rep. No. 100-83*, at 46 (1987) (“Because of our obligations under the GATT treaty to refrain from trade discrimination, the process patent bill was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made (and the process used) in this country or in a foreign country.”); *see also S. Rep. No. 98-663*, at 5 (1984) (observing that the language of an analogous prior legislative proposal “cover[s] products made by the patented process either in the United States or abroad … to avoid any appearance of discrimination against foreign manufacturers”).⁹

⁸ Given this authority, the Commission’s observation (in a footnote) that “§ 271(g) only applies to imported products made abroad by patented processes,” JA199.119 n.61; JA142 n.61, is an incorrect reading of the statute. The Commission’s comment that this Court has not applied section 271(g) “to conduct that is entirely domestic (*i.e.*, with no importation),” *id.*, is beside the point. Here, Intervenors practice several steps of the Group IV patents abroad, prior to importation; only the last claimed process step is practiced subsequently in the United States. JA199.109; JA132; JA199.116-199.117; JA140-41.

⁹ Section 271(g) also “does not require that the process used to make the imported

C. This Court’s Decision in *Kinik Co. v. ITC* Supports Applying 35 U.S.C. § 271(g) in Section 337 Proceedings.

The Commission’s reliance, *see JA199.117-199.119; JA141-42*, on this Court’s decision in *Kinik Co. v. ITC*, 362 F.3d 1359 (Fed. Cir. 2004), to overrule the ALJ’s finding of a violation of the Group IV claims is also unavailing. *Kinik*’s holding was directed to a section 337(a)(1)(B)(ii) violation analysis while the asserted violation of the Group IV claims is under section 337(a)(1)(B)(i).

In *Kinik*, this Court held that the statutory defenses to infringement under section 271(g) are not available in section 337(a)(1)(B)(ii) actions before the Commission. 362 F.3d at 1362-63. The Court based this conclusion on two factors. First, the Court looked to the plain language of the law, observing that “§ 271(g), in the clause introducing new defenses to infringement by overseas practice, states that they are ‘for purposes of this title.’” *Id.* at 1362 (emphasis added). Second, the Court looked to the legislative purpose behind this language

product be … performed by a single entity.” *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1314 (Fed. Cir. 2012), *rev’d on other grounds*, *Limelight Networks, Inc. v. Akamai Techs. Inc.*, 134 S. Ct. 2111 (2014); *see also Trustees of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 108-09 (D. Mass. 2002) (finding an entity liable for infringement under section 271(g) even though another entity manufactured the products); *E.I. DuPont de Nemours & Co. v. Monsanto Co.*, 903 F. Supp. 680, 731-34 (D. Del. 1995) (where one entity performed the first step of a claimed three-step process, and another party performed the last two steps, the first entity was “clearly liable under § 271(g”)), *aff’d*, 92 F.3d 1208 (Fed. Cir. 1996). Consequently, section 271(g) (through section 337(a)(1)(B)(i)) would apply here, where Intervenors, acting in concert, practice all the steps of the Group IV patents, in an arrangement the ALJ found in a related investigation to be a “sham.” JA199.108-199.109; JA132-33; JA1483.

— namely, Congress’s “intent to preserve all existing remedies” then available under the law and not to limit “in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission” *Id.* at 1362-63 (quoting S. Rep. No. 100-83, at 60-61 and citing Pub. L. 100-48, § 9006(c)), and found the product-by-process provisions of section 337(a)(1)(B)(ii) to be just such an existing remedy. *Kinik* concluded that this separation of 35 U.S.C. § 271(g)’s defenses from a violation analysis under 19 U.S.C. § 1337(a)(1)(B)(ii) “served to avert conflict between the Patent Act and the Tariff Act.” 362 F.3d at 1362.

The Commission seeks to drastically expand *Kinik*’s holding to create a segregated world where product-by-process patent holders may only access the 35 U.S.C. § 271(g)’s definition of infringement before a district court, but not the Commission. Specifically, the Commission argues that *Kinik* mandates the conclusion that section 271(g) “was intended to serve *as a supplement in district courts* analogous to the practice at the Commission,” while “the re-enactment of Section 337a as Section 337(a)(1)(B)(ii) was intended to govern practice at the Commission regarding process patents.” JA199.118 (emphasis added); JA142.

Kinik’s analysis, however, points the other way. If, as the Commission urges, “§ 271(g) does not apply to Section 337” at all, JA199.118; JA142, the *Kinik* court could have simply said as much. It would have had no need to parse the text of section 271(g)’s clause setting forth the statutory defenses and

emphasize the importance of Congressional instruction that these defenses only apply “for purposes of this title,” *i.e.* Title 35. 35 U.S.C. § 271(g). The fact that Congress so limited section 271(g) defenses does not mandate the conclusion that the *offensive* use of section 271(g)’s infringement provision should be similarly limited.

Indeed, the plain text of section 271(g) supports a contrary construction. The “this title” limitation identified by *Kinik*, which appears in the clause of section 271(g) setting forth the statutory defenses, is not present in the initial, definitional sentence of section 271(g), which provides that importation of a “product … made by a process patented in the United States” shall constitute an act of infringement. 35 U.S.C. § 271(g).¹⁰ Where Congress uses different language in adjoining portions of the same statute, Congress does so deliberately, and it would be improper to read that term into the statutory clause where Congress omitted it. *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (“when ‘Congress includes particular language in one section of a statute but omits it in another’ — let alone in the very next provision — this Court ‘presume[s]’ that

¹⁰ Section 271(g) also contains another reference to “this title,” in the section’s second sentence, which provides that the patent-holder must first seek remedy from the importer or wholesaler, before seeking relief from the users or retailers of the infringing product. *See H.R. Rep. 100-60*, at 13. Again, this demonstrates that where Congress wanted to specify the applicability of a particular clause of section 271(g), it knew how to do so. *Custis v. United States*, 511 U.S. 485, 492 (1994); *Crawford Fitting Co. v. J. T. Gibbons, Inc.*, 482 U.S. 437, 442 (1987); *Wilson v. Gibson*, 753 F.3d 1363, 1367 (Fed. Cir. 2014).

Congress intended a difference in meaning”, (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983), (alteration in original); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2583 (2012) (“Where Congress uses certain language in one part of a statute and different language in another, it is generally presumed that Congress acts intentionally”) (citing *Russello*, 464 U.S. at 23); 2A *Sutherland on Statutory Construction* § 46:6, at 251-252 (“where the legislature has employed a term in one place and excluded it in another, it should not be implied where excluded”).

The fact that Congress used the “this title” limitation elsewhere in section 271(g), but did not do so in the provision’s definitional clause, indicates that Congress *did not intend* — as the Commission suggests — to limit its definition of infringement by products made by a patented process solely for Title 35 actions. *See Russello*, 464 U.S. at 23 (“[h]ad Congress intended to restrict [a statutory subsection] to an interest in an enterprise, it presumably would have done so expressly as it did in the immediately following subsection”); *Sioux Honey Ass'n v. Hartford Fire Ins. Co.*, 672 F.3d 1041, 1052 (Fed. Cir.), *cert. denied*, 133 S. Ct. 126 (2012). Indeed, nothing in section 271(g)’s statutory language would support a reading of that section as implicitly excluding the act of infringement defined in that section from Commission proceedings under 19 U.S.C. § 1337(a)(1)(B)(i).

The Commission also relies, *see* JA199.118; JA142-43, on *Kinik*’s

observation, derived from section 271(g)'s legislative history, that “§ 271(g) was intended to provide ‘patent owners the new right to sue for damages and seek an injunction in Federal district court.’” 362 F.3d at 1362 (quoting S. Rep. No. 100-83, at 29 (1987)). As an initial matter, inferences from legislative history cannot outweigh the plain language of the statute. *Chamber of Commerce of United States v. Whiting*, 131S.Ct. 1968, 1980 (2011); *United States v. Gonzales*, 520 U.S. 1, 6 (1997); *Toibb v. Radloff*, 501 U.S. 157, 162 (1991); *Van Wersch v. Dep’t of Health & Human Servs.*, 197 F.3d 1144, 1152 (Fed. Cir. 1999). In any event, the fact that Congress provided patent-holders with additional judicial fora and remedies against the practice of processes patented in the United States does not mean that Congress implicitly intended *to exclude* the newly defined acts of infringement under 35 U.S.C. § 271 from the scope of what constitutes “articles that infringe” in section 337(a)(1)(B)(i). Such an inference of an implied exception is not only disfavored, *see United States v. Rutherford*, 442 U.S. 544, 555 (1979) (“Only when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language be judicially implied.”), but is also contrary to the congressional concern that the new section 271(g) not “limit in any way the ability of process patent owners to obtain relief” in section 337 proceedings. S. Rep. No. 100-83, at 60-61, *quoted in Kinik*, 362 F.3d at 1363.

The Commission's contorted interpretation of section 337(a)(1)(B)(i) would unnecessarily impair the ability of patent-holders to address joint global business operations contrived specifically in an attempt to avoid infringement liability. This Court should correct the Commission's erroneous interpretation of section 337 (rooted in a misreading of this Court's decision in *Kinik*), and reaffirm that section 337(a)(1)(B)(i) authorizes the Commission to reach all acts that constitute "importation ... of articles that infringe" under the provisions of the Patent Act. Thus, the Commission's interpretation is not only contrary to the plain language, but unreasonable.

CONCLUSION

This Court should reverse the Commission's finding of no violation with respect to the Group III and Group IV patent claims asserted by Align.

Respectfully submitted,

Dated: October 9, 2014

By: /s/Igor V. Timofeyev

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*Counsel for Appellant
Align Technology, Inc.*

CERTIFICATE OF SERVICE

I, Igor V. Timofeyev, hereby certify that, on October 9, 2014, the foregoing document was filed using the CM/ECF system and served on the parties of record via ECF.

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Dated: October 9, 2014

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**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS,
AND TYPE STYLE REQUIREMENTS**

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and this Court's Rule 28(a)(14), I certify the following:

1. The attached Brief of Appellant Align Technology, Inc. complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 11,929 words (according to the Microsoft Word 2010 count function), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. The attached Brief of Appellant Align Technology, Inc. complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally space typeface using Microsoft Word 2010 in 14-point Times New Roman type style.

DATED: October 9, 2014 By:

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ADDENDUM

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Investigation No. 337-TA-833

NOTICE OF COMMISSION DETERMINATION TO AFFIRM-IN-PART, MODIFY-IN-PART, AND REVERSE-IN-PART THE FINAL INITIAL DETERMINATION AND TO FIND A VIOLATION OF SECTION 337; ISSUANCE OF CEASE AND DESIST ORDERS; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final initial determination (“final ID” or “ID”), and to find a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”) in the above-captioned investigation. The Commission has issued cease and desist orders.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc., of San Jose, California (“Align”), on March 1, 2012, as corrected on March 22, 2012. 77 Fed. Reg. 20648 (April 5,

2012). The complaint alleged violations of Section 337 in the sale for importation, importation, or sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances, the appliances made therefrom, and methods of making the same by reason of infringement of certain claims of U.S. Patent No. 6,217,325 ("the '325 patent"); U.S. Patent No. 6,471,511 ("the '511 patent"); U.S. Patent No. 6,626,666 ("the '666 patent"); U.S. Patent No. 6,705,863 ("the '863 patent"); U.S. Patent No. 6,722,880 ("the '880 patent"); U.S. Patent No. 7,134,874 ("the '874 patent"); and U.S. Patent No. 8,070,487 (the '487 patent"). The notice of institution named as respondents ClearCorrect Pakistan (Private), Ltd. of Lahore, Pakistan ("CCPK") and ClearCorrect Operating, LLC of Houston, Texas ("CCUS") (collectively, "the Respondents").

On May 6, 2013, the presiding administrative law judge ("ALJ") issued the final ID, finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, '863 patent, and the '874 patent. He found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to the Respondents.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 16, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013.

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 Fed. Reg. 46611 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013.

On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On January 17, 2014, the Commission determined to extend the target date for completion of the above-captioned investigation to March 21, 2014, and to solicit additional briefing from the parties and the public.

On March 21, 2014, the Commission issued notice of its determination to extend the target date for completion of the investigation to April 3, 2014.

After considering the ID and the relevant portions of the record, and the submissions of the parties and the public, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final ID and to find a violation of Section 337. The Commission has issued its opinion setting forth the reasons for its determination. Commissioner Johanson dissents and has filed a dissenting opinion.

Specifically, the Commission affirms the ALJ's conclusion that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B). The Commission has determined to find a violation with respect to (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. The Commission has issued cease and desist orders directed to CCUS and CCPK, with an exemption for activities related to treatment of existing patients in the United States. The investigation is hereby terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Investigation No. 337-TA-833

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT ClearCorrect Operating, LLC, 15151 Sommermeyer Street, Houston, Texas, 77041-5332, cease and desist from conducting any of the following activities in the United States: (1) importing (including through electronic transmission); (2) marketing, selling, distributing, and transferring (including through electronic transmission, except for exportation); (3) advertising in the United States; and (4) soliciting U.S. agents or distributors for digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances or the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of U.S. Patent No. 6,705,863 ("the '863 patent"); (ii) claims 1, 3, 7, and 9 of U.S. Patent No. 6,626,666 ("the '666 patent"); (iii) claims 1, 3, and 5 of U.S. Patent No. 8,070,487 ("the '487 patent"); (iv) claims 21, 30, 31 and 32 of U.S. Patent No. 6,217,325 ("the '325 patent"); and (v) claim 1 of U.S. Patent No. 6,722,880 ("the '880 patent") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I.
Definitions

As used in this order:

- (A) "Commission" shall mean the United States International Trade Commission.
- (B) "Complainant" shall mean Align Technology, Inc. of San Jose, California.
- (C) "Respondent" shall mean ClearCorrect Operating, LLC, 15151 Sommermeyer Street, Houston, Texas, 77041-5332.
- (D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States; the terms also refer to the electronic transmission of covered products in whatever form, into the United States.
- (G) The term "covered products" shall mean digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances and the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. Covered products shall not include

articles for which a provision of law or license avoids liability for the infringement of the claims listed above.

- (H) The term “covered process” shall mean the use of methods of making digital models, digital data, and treatment plans, for use in making incremental dental positioning adjustment appliances, that infringe claims of (i) claims 1 and 4-8 of the ‘863 patent; (ii) claims 1, 3, 7, and 9 of the ‘666 patent; (iii) claims 1, 3, and 5 of the ‘487 patent; (iv) claims 21, 30, 31 and 32 of the ‘325 patent; and (v) Group I: claim 1 of the ‘880 patent.
- (I) The phrase “products made using imported covered products” shall include any appliances (including without limitation, initial, intermediate and/or final) made by a covered process using the digital models, digital data, or treatment plans imported by Respondents.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

**III.
Conduct Prohibited**

The following conduct of Respondent in the United States is prohibited by this Order.

For the remaining term of the relevant '666 patent, '863 patent, '487 patent, '325 patent, or '880 patent, or Respondent shall not:

- (A) import (including through electronic transmission or otherwise) or sell for importation into the United States covered products; or use, duplicate, transfer (except for exportation), in the United States imported covered products or any products made using imported covered products;
- (B) market, distribute, sell, or otherwise transfer (including through electronic transmission) in the United States (except for exportation) imported covered products or any products made using covered products;
- (C) advertise imported covered products or any products made using imported covered products;
- (D) solicit U.S. agents, distributors, or purchasers for imported covered products or any products made using imported covered products; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products or any products made using imported covered products.

**IV.
Conduct Permitted**

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '666 patent, '863 patent, '487 patent, '325 patent, and '880 patent licenses or authorizes such specific

conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

This order does not apply to activity related to treatment of patients who have begun treatment or signed a contract for treatment with covered products or any products made using imported covered products on or before April 10, 2014. Also exempted from this order are activities related to the repair, replacement, or refurbishment of covered products that were imported prior to April 10, 2014.

**V.
Reporting**

For purposes of this requirement, the reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2014. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no transfers of covered products or any products made using imported covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and the number of patients receiving treatment or replacement products, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. Respondent shall also include a certification that the imported products are for patients who were receiving treatment or who had signed a contract for treatment before April 10, 2014, and that replacement products are for products that were

previously imported before April 10, 2014. When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-833") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainants' counsel.¹

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. **Record-Keeping and Inspection**

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products and any products made using imported covered products, made and received in the usual and ordinary course of business,

¹ Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

Respondent is ordered and directed to:

- (A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products and any products made using imported covered products in the United States;
- (B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration dates of the '666 patent, '863 patent, '487 patent, '325 patent, and '880 patent.

**VIII.
Confidentiality**

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

**IX.
Enforcement**

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 *Fed. Reg.* 43,251 (Jul. 21, 2005)), without Respondent posting a bond.

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING THE SAME

Investigation No. 337-TA-833

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT ClearCorrect Pakistan (Private), Ltd., Azia Cottage, 9-Kanal Park, Gulberg II, Lahore, Pakistan, cease and desist from conducting any of the following activities in the United States: (1) importing (including through electronic transmission); (2) marketing, selling, distributing, and transferring (including through electronic transmission, except for exportation); (3) advertising in the United States; and (4) soliciting U.S. agents or distributors for digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances or the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of U.S. Patent No. 6,705,863 ("the '863 patent"); (ii) claims 1, 3, 7, and 9 of U.S. Patent No. 6,626,666 ("the '666 patent"); (iii) claims 1, 3, and 5 of U.S. Patent No. 8,070,487 ("the '487 patent"); (iv) claims 21, 30, 31 and 32 of U.S. Patent No. 6,217,325 ("the '325 patent"); and (v) claim 1 of U.S. Patent No. 6,722,880 ("the '880 patent") in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

I.
Definitions

As used in this order:

- (A) "Commission" shall mean the United States International Trade Commission.
- (B) "Complainant" shall mean Align Technology, Inc. of San Jose, California.
- (C) "Respondent" shall mean ClearCorrect Pakistan (Private), Ltd., Azia Cottage, 9-Kanal Park, Gulberg II, Lahore, Pakistan.
- (D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.
- (E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States; the terms also refer to the electronic transmission of covered products in whatever form, into the United States.
- (G) The term "covered products" shall mean digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances and the appliances made therefrom covered by one or more of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) claim 1 of the '880 patent. Covered products shall not include

articles for which a provision of law or license avoids liability for the infringement of the claims listed above.

- (H) The term "covered process" shall mean the use of methods of making digital models, digital data, and treatment plans, for use in making incremental dental positioning adjustment appliances, that infringe claims of (i) claims 1 and 4-8 of the '863 patent; (ii) claims 1, 3, 7, and 9 of the '666 patent; (iii) claims 1, 3, and 5 of the '487 patent; (iv) claims 21, 30, 31 and 32 of the '325 patent; and (v) Group I: claim 1 of the '880 patent.
- (I) The phrase "products made using imported covered products" shall include any appliances (including without limitation, initial, intermediate and/or final) made by a covered process using the digital models, digital data, or treatment plans imported by Respondents.

II. **Applicability**

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

**III.
Conduct Prohibited**

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of the relevant '666 patent, '863 patent, '487 patent, '325 patent, or '880 patent, or Respondent shall not:

- (A) import (including through electronic transmission or otherwise) or sell for importation into the United States covered products; or use, duplicate, transfer (except for exportation), in the United States imported covered products or any products made using imported covered products;
- (B) market, distribute, sell, or otherwise transfer (including through electronic transmission) in the United States (except for exportation) imported covered products or any products made using covered products;
- (C) advertise imported covered products or any products made using imported covered products;
- (D) solicit U.S. agents, distributors, or purchasers for imported covered products or any products made using imported covered products; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of covered products or any products made using imported covered products.

**IV.
Conduct Permitted**

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if, in a written instrument, the owner of the '666

patent, '863 patent, '487 patent, '325 patent, and '880 patent licenses or authorizes such specific conduct, or such specific conduct is related to the importation or sale of covered products by or for the United States.

This order does not apply to activity related to treatment of patients who have begun treatment or signed a contract for treatment with covered products or any products made using imported covered products on or before April 10, 2014. Also exempted from this order are activities related to the repair, replacement, or refurbishment of covered products that were imported prior to April 10, 2014.

**V.
Reporting**

For purposes of this requirement, the reporting periods shall commence on July 1 of each year and shall end on the subsequent June 30. The first report required under this section shall cover the period from the date of issuance of this order through June 30, 2014. This reporting requirement shall continue in force until such time as Respondent has truthfully reported, in two consecutive timely filed reports, that it has no transfers of covered products or any products made using imported covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and the number of patients receiving treatment or replacement products, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period. Respondent shall also include a certification that the

imported products are for patients who were receiving treatment or who had signed a contract for treatment before April 10, 2014, and that replacement products are for products that were previously imported before April 10, 2014. When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-833") in a prominent place on the cover pages and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainants' counsel.¹

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Record-Keeping and Inspection

- (A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in

¹ Complainants must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

the United States of covered products and any products made using imported covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

Respondent is ordered and directed to:

- (A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, or sale of imported covered products and any products made using imported covered products in the United States;

- (B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration dates of the '666 patent, '863 patent, '487 patent, '325 patent, and '880 patent.

**VIII.
Confidentiality**

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

**IX.
Enforcement**

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as delegated by the President (*70 Fed. Reg. 43,251* (Jul. 21, 2005)), without Respondent posting a bond.

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: April 3, 2014

Page 1 – Certificate of Service

**CERTAIN DIGITAL MODELS, DIGITAL DATA, AND
TREATMENT PLANS FOR USE, IN MAKING
INCREMENTAL DENTAL POSITIONING ADJUSTMENT
APPLIANCES, THE APPLIANCES MADE THEREFROM,
AND METHODS OF MAKING THE SAME**

337-TA-833

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on April 3, 2014.



Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

On Behalf of Complainant:

Scott M. Flicker, Esq. () Via Hand Delivery
PAUL HASTINGS LLP (✓) Via Express Delivery
 875 15th Street, NW () Via First Class Mail
 Washington, DC 20005 () Other: _____

On Behalf of Clearcorrect Operating, LLC:

Gary M. Hnath, Esq. () Via Hand Delivery
MAYER BROWN LLP (✓) Via Express Delivery
 1999 K Street, NW () Via First Class Mail
 Washington, DC 20006 () Other: _____

On Behalf of Clearcorrect Pakistan (Private), Ltd.:

Lei Mei, Esq. () Via Hand Delivery
MEI & MARK LLP (✓) Via Express Delivery
 818 18th Street NW, Suite 410 () Via First Class Mail
 Washington, DC 20006 () Other: _____

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN DIGITAL MODELS, DIGITAL
DATA, AND TREATMENT PLANS FOR USE
IN MAKING INCREMENTAL DENTAL
POSITIONING ADJUSTMENT APPLIANCES,
THE APPLIANCES MADE THEREFROM,
AND METHODS OF MAKING THE SAME**

Investigation No. 337-TA-833

COMMISSION OPINION

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PUBLIC VERSION

Abbreviation	Full Name
ID	Initial Determination
RD	Recommended Determination
Align Pet.	Complainant Align Technology, Inc.'s Petition and Contingent Petition for Review of the Initial Determination
Resps. Pet.	Respondents' Petition for Review
IA Pet.	Petition of the Office of Unfair Import Investigations for Review of the Initial Determination on Violation of Section 337
Align Resp. to Resps.	Complainant Align Technology, Inc.'s Response to Respondents' Petition for Review of the Initial Determination
Align Resp. to IA	Complainant Align Technology, Inc.'s Response to the Office of Unfair Import Investigations' Petition for Review of the Initial Determination
Resps. Resp.	Respondents' Response to Align's Petition for Review and Contingent Petition for Review of the Initial Determination and Response to Petition of the Office of Unfair Import Investigations for Review of the Initial Determination
IA Resp.	Response of the Office of Unfair Import Investigations to the Private Parties' Petitions for Review of the Initial Determination on Violation of Section 337
Align Sub.	Complainant Align Technology, Inc.'s Written Submission on Issues Under Review and on Remedy, the Public Interest and Bonding
Resps. Sub.	Respondents' Response to the Notice of the Commission's Determination to Review the Final Initial Determination of the Administrative Law Judge
IA Sub.	Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on Issues Under Review
Align Reply Sub.	Complainant Align Technology, Inc.'s Reply to Respondents' and Staff's Written Submissions on Issues Under Review and on Remedy, Public Interest and Bonding
Resps. Reply Sub.	Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ and Exhibits
IA Reply Sub.	Response of the Office of Unfair Import Investigations to Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding
Align Add. Sub.	Complainant Align Technology, Inc.'s Written Submission on the Commission's January 17, 2014 Questions
Resps. Add. Sub.	[Respondents'] Response to the Commission's January 17, 2014 Notice

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IA Add. Sub.	OUII's Response to the Commission's Request for Additional Written Submissions
MPAA Sub.	Submission on Behalf of Motion Picture Association of America in Response to Commission's January 17, 2014 Notice
Google Sub.	Submission of Non-Party Google Inc. in Response to Commission's Request for Public Comments
Katz Sub.	Memorandum Providing Public Comment In Response To Notice Of Commission Determination To Extend The Target Date For Completion Of The Investigation; Schedule For Filing Of Additional Written Submissions From The Parties And The Public
Align. Reply Add. Sub.	Complainant Align Technology, Inc.'s Reply Written Submission on the Commission's January 17, 2014 Questions
Resps. Reply Add. Sub.	Respondents' Non-Confidential Reply to Written Submissions in Response to the Commission's January 17, 2014 Notice
IA Reply Add. Sub.	Response of the Office of Unfair Import Investigations to the Additional Written Submissions from the Parties and the Public
MPAA Reply Sub.	Reply Comments Filed on Behalf of Motion Picture Association of America
AAP Sub.	Association of American Publishers Reply Comments
Nokia Sub.	Reply Written Submission of Non-Party Nokia Corp. to the Submissions in Response to the Commission's Request for Public Comments

PUBLIC VERSION

On May 6, 2013, the presiding administrative law judge (“ALJ”) (Judge Rogers) issued his final initial determination (“ID”) in this investigation, finding a violation of Section 337.

Having considered the ID, the submissions of the parties and the public, and the relevant portions of the record, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the final ID. The Commission has determined that the Respondents have violated Section 337 in the importation, sale for importation, or sale after importation of digital models, digital data, and treatment plans for use in making incremental dental appliances. Commissioner Johanson dissents.¹ The Commission has determined to adopt the ALJ’s findings that are consistent with the Commission’s opinion as set forth below.

I. BACKGROUND**A. Procedural History**

This investigation was instituted on April 5, 2012, based upon a complaint filed on behalf of Align Technology, Inc. (“Align”) of San Jose, California on March 1, 2012, and a corrected complaint filed on March 22, 2012. *77 Fed. Reg. 20648-49* (April 5, 2012). The complaint, as corrected, alleged violations of section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital models, digital data, and treatment plans for use in making incremental dental appliances by reason of infringement of U.S. Patent No. 6,217,325 (“the ‘325 patent”), U.S. Patent

¹ Commissioner Johanson has filed a dissenting opinion, post.

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No. 6,722,880 ("the '880 patent"), U.S. Patent No. 8,070,487 ("the '487 patent"), U.S. Patent No. 6,471,511 ("the '511 patent"), U.S. Patent No. 6,626,666 ("the '666 patent"), U.S. Patent No. 6,705,863 ("the '863 patent") and U.S. Patent No. 7,134,874 ("the '874 patent"). The notice of investigation named as respondents ClearCorrect Operating, LLC ("ClearCorrect USA" or "CCUS") and ClearCorrect Pakistan (Private), Ltd ("ClearCorrect Pakistan" or "CCPK"). A Commission investigative attorney ("IA") participated in this investigation.

On January 14, 2013, the ALJ issued Order No. 20, denying CCUS's and CCPK's motion for summary determination that certain asserted claims were not infringed and that claim 1 of the '880 patent was invalid, and finding that CCUS and CCPK waived any estoppel defense, including defenses based on implied license or patent exhaustion.

On May 6, 2013, the ALJ issued the final ID, finding a violation of Section 337 with respect to the '325 patent, the '880 patent, the '487 patent, the '511 patent, '863 patent, and the '874 patent. The ALJ found no violation as to the '666 patent. The ALJ recommended the issuance of cease and desist orders directed to CCUS and CCPK to prohibit the importation of digital data sets.

On May 20, 2013, each of the parties filed a petition for review. On May 28, 2013, each of the parties filed a response thereto.

On June 5, 2013, Align filed a statement on the public interest. On June 13, 2013, the Respondents filed a statement on the public interest.

On June 7, 2013, the Commission issued notice of its determination to extend the deadline for determining whether to review the final ID to July 25, 2013, and to extend the target date to September 24, 2013.

PUBLIC VERSION

On July 25, 2013, the Commission issued notice of its determination to review the final ID in its entirety and to solicit briefing on the issues on review and on remedy, the public interest, and bonding. 78 Fed. Reg. 46611-12 (August 1, 2013). On August 8, 2013, each of the parties filed written submissions. On August 15, 2013, each filed reply submissions.

On September 24, 2013, the Commission issued notice of its determination to extend the target date to November 1, 2013. Due to the federal government shutdown and the Commission Notice tolling all deadlines by the length of the shutdown, the target date became November 18, 2013. On November 18, 2013, the Commission issued notice of its determination to extend the target date to January 17, 2014.

On December 31, 2013, the Respondents filed a notice of supplemental authority. On January 10, 2014, Align filed a reply thereto.

On January 17, 2014, the Commission issued a notice extending the target date to March 21, 2014, and soliciting further briefing from the public and the parties. 79 Fed. Reg. 4174-74 (January 24, 2014).

On February 3, 2014, the Commission received written submissions from each of the parties and from Motion Picture Association of America (“MPAA”), Google Inc. (“Google”), and Andrew Katz (Mr. Katz).² On February 10, 2014, the Commission received reply submissions from each of the parties and from MPAA, the Association of American Publishers (“the AAP”), and Nokia Corporation (“Nokia”).

On March 21, 2004, the Commission issued notice of its determination to extend the target date to April 3, 2014.

² Mr. Katz is an attorney of the law firm Belles Katz LLC in Horsham, Pennsylvania.

PUBLIC VERSION**B. Related Cases**

On February 15, 2006, the Commission instituted an original investigation captioned *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (“the 562 investigation”), based on a complaint also filed by Align. 71 Fed. Reg. 7995-96 (February 15, 2006). Briefly, the complaint alleged that the OrthoClear Respondents³ violated Section 337 when they imported and sold aligners in the United States which had been manufactured in Pakistan. The orthodontic aligners at issue were accused of infringing the ‘880 and ‘511 patents asserted in this investigation, among numerous others. *Id.*

On October 27, 2006, the presiding ALJ issued an Initial Determination granting Align’s and OrthoClear’s joint motion to terminate the investigation based on a consent order. The Commission determined not to review the ID. Notice (November 13, 2006).

The consent order provides in relevant part:

1. The incremental dental positioning adjustment appliances manufactured by or for OrthoClear referenced in the complaint and any other articles manufactured in violation of the patents or trade secrets described therein (the “Articles”) are hereby prohibited from importation into the United States until the expiration of the last to expire of the following patents: (i) U.S. Patent No. 6,685,469 (“the ‘469 patent”); (ii) U.S. Patent No. 6,394,801 (“the ‘801 patent”); (iii) U.S. Patent No. 6,398,548 (“the ‘548 patent”); (iv) U.S. Patent No. 6,722,880 (“the ‘880 patent”); (v) U.S. Patent No. 6,629,840 (“the ‘840 patent”); (vi) U.S. Patent No. 6,699,037 (“the ‘037 patent”); (vii) U.S. Patent No. 6,318,994 (“the ‘994 patent”); (viii) U.S. Patent No. 6,729,876 (“the ‘876 patent”); (ix) U.S. Patent No. 6,602,070 (“the ‘070 patent”); (x) U.S. Patent No. 6,471,511 (“the ‘511 patent”); and (xi) U.S. Patent No. 6,227,850 (“the ‘850 patent”) (collectively “the Patents-In-Suit”), except under license of the patent owner or as provided by law.

³ The Commission’s notice of investigation named OrthoClear, Inc. of San Francisco, California; OrthoClear Holdings, Inc. of Tortola, British Virgin Islands; and OrthoClear Pakistan Pvt, Ltd. of Lahore, Pakistan (collectively, “OrthoClear”) as respondents.

PUBLIC VERSION

2. Upon entry of this Consent Order, OrthoClear shall not sell for importation, import into the United States, or sell in the United States after importation the Articles, or knowingly aid, abet, encourage, participate in, or induce the sale for importation into the United States or sale in the United States after importation of the Articles.

3. This Consent Order shall be applicable and binding upon OrthoClear, its officers, directors, agents, servants, employees, successors and assigns, and all persons, firms, or corporations acting or claiming to act on its behalf or under its direction or authority.

On March 1, 2012, Align filed a complaint for an enforcement proceeding under Commission Rule 210.75, 19 C.F.R. § 210.75, which was instituted on April 25, 2012 (“the 562 Enforcement Proceeding”). Align based its complaint on alleged violations of the consent order by ClearCorrect USA of Houston, Texas (“CCUS”); ClearCorrect Pakistan (Private), Ltd. (“CCPK”) of Lahore, Pakistan; and Mudassar Rathore, Waqas Wahab, Nadeem Arif, and Asim Waheed (collectively, “Enforcement Respondents”). 77 Fed. Reg. 25747 (May 1, 2012).

In the complaint for enforcement, Align alleged that the Enforcement Respondents violated the consent order when they sold for importation, imported, or sold after importation digital data sets, including digital models of a patient’s teeth, digital data and/or treatment paths transmitted (electronically) to the United States, and subsequently manufactured aligners in the United States using those imported digital data sets. According to Align, the Enforcement Respondents’ use of certain processes, systems, and techniques infringe at least claim 1 of the ‘511 patent and claims 1 and 3 of the ‘880 patent. Enforcement Complaint ¶ 90, 94-95.

PUBLIC VERSION

Align further alleged that both CCUS and CCPK are “successor[s], assign[s], or agent[s]” of the original OrthoClear respondents. *Id.* ¶ 24, 31.⁴ The complaint also alleges that the named individuals are former employees or a director of OrthoClear. Enforcement Complaint ¶¶ 34, 38, 42, 46. ClearCorrect Pakistan admits that the individuals are former employees of OrthoClear and further admits that Mudassar Rathore is the CEO of CCPK, Waqas Wahab and Nadeem Arif are directors of orthodontics for CCPK, and that Asim Waheed is a manager of quality control at CCPK. Response of CCUS to Enforcement Complaint ¶¶ 34-35, 38-39, 42-43, 46-47.

On November 28, 2012, the ALJ issued Order No. 57, finding that the accused digital data sets are “articles manufactured” within the meaning of paragraph 1 of the consent order. On January 4, 2013, the Commission issued notice of its determination to review and reverse the ID and to terminate the proceeding with a finding of no violation of the consent order. 78 Fed. Reg. 2282-83 (January 10, 2013). In its opinion, the Commission held that, since the consent order at issue contained no express provision for electronic transmissions, the consent order did not cover electronic transmissions under Commission precedent and thus there was no violation of the consent order. *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Comm'n Op. (January 23, 2013). Align has appealed the Commission's determination from the 562 Enforcement Proceeding to the U.S. Court of Appeals for the Federal Circuit. Case Nos. 2013-1240, -1363. That appeal is currently pending.

⁴ ClearCorrect USA and ClearCorrect Pakistan have denied these allegations. Response of CCUS to Enforcement Complaint ¶ 24; Response of CCPK to Enforcement Complaint ¶ 31.

PUBLIC VERSION**C. The Patents**

Align asserts seven U.S. patents that all claim priority to provisional application No. 60/050,342 filed on June 20, 1997. As with the specifications of all the patents in suit, each patent is directed towards a system for repositioning teeth comprising a plurality of individual appliances (aligners) which are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement to a final tooth arrangement.⁵ See, e.g., '880 Patent Abstract.⁶ While the seven asserted patents all share a common inventive concept of using digital data sets to construct the individual appliances, a description of each asserted patent is set forth below.

I. The '325 Patent

The '325 patent,⁷ entitled "Method and System For Incrementally Moving Teeth," issued on April 17, 2001, based on Application No. 09/298,268, filed by Muhammad Chishti, Apostolos Lerios, Brian Freyburger, Kelsey Wirth, and Richard Ridgley on April 23, 1999. ID at 2-3. The '325 patent is a divisional of non-asserted U.S. Patent No. 5,975,893 filed Oct. 8, 1997. The '325 patent was the subject of an ex parte reexamination based on a request received on July 27, 2005, that added limitations to original claims 1 and 18-21 and added new claims 27-39. *Id.* A reexamination certificate issued on January 15, 2008. *Id.*

⁵ The asserted patents note that "the appliances can be braces, polymeric shells, or other forms of orthodontic appliances." '511 patent Abstract.

⁶ The asserted patents have different specifications, but are from the same family.

⁷ JX-3.

PUBLIC VERSION

Align has asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39. Claims 1, 11, 21, 31, 35 and 38 are independent claims. Certain claims of the ‘325 patent are directed to a method for fabricating a plurality of dental incremental position adjustment appliances using digital data sets representing an initial tooth arrangement, a final tooth arrangement, and a series of intermediate digital data sets representing the tooth arrangements progressing from the initial to the final arrangement. ‘325 patent, col. 16, lines 19-34.

Claim 1 recites:

1. A method for facilitating a tooth repositioning dental treatment, including producing a plurality of digital sets representing a plurality of tooth arrangements, said method comprising:

- providing an intial digital data set representing an initial tooth arrangement;
- presenting a visual image based on the initial data set;
- manipulating the visual image to reposition individual teeth in the visual image;
- producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;
- producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
- fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

Id. Ex Parte Rexam Cert. at col. 1, lines 29-48.

2. The ‘880 Patent

The ‘880 patent,⁸ entitled “Method and System for Incrementally Moving Teeth,” issued on April 20, 2004, based on Application No. 10/047,077, filed by Muhammad Chishti and Kelsey Wirth on January 14, 2002. ID at 3. The ‘880 patent arises from an

⁸ JX-2.

PUBLIC VERSION

application which is a continuation-in-part of a related, non-asserted patent. Align has asserted claims 1 and 3; claim 1 is an independent claim.

Similar in manner to the '325 patent, claim 1 of the '880 patent is directed to a method for fabricating dental adjustment appliances using digital data sets. The asserted claims of the '880 patent expressly define the "dental adjustment appliances" as comprising "polymeric shells having cavities shaped to receive and resiliently reposition teeth." '880 patent, col. 22, lines 12-29. Claim 1 recites:

1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
 - a) obtaining a digital data set representing an initial tooth arrangement;
 - b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;
 - c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and
 - d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

Id. Dependent claim 3 teaches that the digital data set is obtained by defining boundaries of the individual teeth and moving at least some of the tooth boundaries relative to other teeth in an image. *Id.* col. 22, lines 33-41. Claim 3 recites:

3. A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:

defining boundaries about at least some of the individual teeth; and
moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

Id.

PUBLIC VERSION**3. The '487 Patent**

The '487 patent,⁹ entitled "System and Method for Positioning Teeth," issued on December 6, 2011, based on Application No. 11/981,680, filed by Muhammad Chishti and Andrew Beers on October 31, 2007. *Id.* at 3. Align has asserted claims 1, 3, 5 and 7-9, of which claims 1 and 7 are independent.

The asserted claims are directed to a method of planning dental treatment by producing digital data sets. The '487 patent teaches the concept of an "orthodontic treatment plan." '487 patent, col. 11, lines 26-35. Claim 1 recites:

1. A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
 receiving an initial digital data set representing an initial arrangement of the patient's teeth;
 producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;
 producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

Id., col. 10, line 61 to col. 11, line 6. In addition, claim 7 provides that the "treatment plan resid[es] on a computer readable media." *Id.*, col. 11, lines 28-29. Claim 7 recites:

7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

⁹ JX-7.

PUBLIC VERSION

Id., col. 11, lines 26-35. Although the ‘487 patent introduces the limitation of “orthodontic treatment plan,” the underlying structure of the claim remains directed to development of digital data sets. *Id.*

4. The ‘511 Patent

The ‘511 patent,¹⁰ entitled “Defining Tooth-Moving Appliances Computationally,” issued on October 29 2002, based on Application No. 09/169,034, filed by Muhammad Chishti, Elena I. Pavlovskaya, Gregory P. Bala and Brian Freyburger on October 8, 1998. ID at 4. The ‘511 patent arises from an application which is a continuation-in-part of a non-asserted patent. The sole asserted claim is claim 1.

The ‘511 patent is directed towards methods for segmenting an orthodontic treatment plan, as referred previously in the ‘487 patent, into clinically appropriate sub-steps for repositioning the teeth of a patient. ‘511 patent, Abstract. The limitations presented in claim 1 of the ‘511 patent are distinguished from the claims of other asserted patents because claim 1 further provides for “calculating a segmentation of the aggregate tooth paths...so that each tooth’s motion stays within threshold limits of linear and rotational translation.” *Id.*, col. 11, lines 9-12. Claim 1 recites:

1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
 - for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;
 - calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth’s motion within a segment stays within threshold limits of linear and rotational translation; and
 - generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of

¹⁰ JX-1.

PUBLIC VERSION

successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

Id., col. 11, lines 4-19.

5. The ‘666 Patent

The ‘666 patent,¹¹ entitled “Method and System for Incrementally Moving Teeth,” issued on September 30, 2003, based on Application No. 09/757,044, filed by Muhammad Chishti, Apostolos Lerior, Brian Freyburger, Kelsey Wirth and Richard Ridgley on January 8, 2001. ID at 4-5. Align has asserted claims 1, 3, 7 and 9; claims 1 and 7 are independent claims.

The claims of the ‘666 patent are directed to a method of producing a “plurality of digital data sets.” ‘666 patent, col. 15, lines 27-48. Similar to the manner of claims for the ‘880 patent, the ‘666 patent produces digital data sets by “moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set.” *Id.* at col. 15, lines 38-40. Claim 1 recites:

1. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

- providing a computer system;
- providing to the computer system an initial digital data set representing an initial tooth arrangement;
- defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
- moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and
- producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth

¹¹ JX-4.

PUBLIC VERSION

arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

Id., col. 15, lines 27-47. Additionally, claim 7 of the ‘666 patent introduces the limitation of “interpolating positional differences between the teeth in the initial and final data sets.”

Id. at col. 16, lines 7-13. Claim 7 recites:

7. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

- providing a computer system;
- providing to the computer system digital data set representing an initial tooth arrangement;
- providing to the computer system a digital data set representing a final tooth arrangement;
- interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

Id., col. 15, line 64 to col. 16, line 13.

6. The ‘863 Patent

The ‘863 patent,¹² entitled “Attachment Devices and Methods for a Dental Appliance,” issued on March 16, 2004, based on Application No. 10/040,269, filed by Loc X. Phan, Muhammad Z. Chishti and Ross J. Miller on October 29, 2001. *ID* at 5. The ‘863 patent was the subject of an ex parte reexamination based on a request received on June 23, 2005. *Id.* The ‘863 patent is a continuation-in-part of a non-asserted U.S. patent 6,309,215 filed Dec. 3, 1999.

Align has asserted claims 1 and 4-8; claim 1 is an independent claim. Claim 1 of the ‘863 patent was subject to ex parte reexamination and is directed towards a method

¹² JX-5.

PUBLIC VERSION

for producing digital models of dental appliances. ‘863 patent, Ex Parte Reexam Cert. col. 1, lines 57-col. 2, line 4. The asserted claims disclose a method of “producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment.” *Id.* Claim 1 recites:

A method for producing digital models of dental positioning appliances, said method comprising:

- providing a digital model of a patient’s dentition;
- producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;
- providing a digital model of at least one attachment device; and
- positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

Id.

7. The ‘874 Patent

The ‘874 patent,¹³ entitled “Computer Automated Development of an Orthodontic Treatment Plan and Appliance,” issued on November 14, 2006, based on Application No. 10/718,779, filed by Muhammad Chishti, Brian Freyburger, Kelsey Wirth, Andrew Beers, Huafeng Wen, Phillips Alexander Benton, Timothy N. Jones, and Ross J. Miller on November 20, 2003. ID at 5-6.

Align has asserted claims 1, 2, 38-39, 41, and 62; claim 1 is an independent claim. Claim 1 of the ‘874 patent is directed to a method for “creating a treatment plan to reposition a patient’s teeth from a set of initial tooth positions to a set of final tooth

¹³ JX-6.

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positions" in a manner similar to the other asserted patents. '874 patent, col. 32, lines 37-

56. Claim 1 recites:

1. A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:

receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof;

generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and

generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,

wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.

Id. In contrast to the other patents in suit, the asserted claims of the '874 patent have a limitation of generating a plurality of appliances "prior to patient wearing any appliance." '874 patent, col. 32, lines 53-56.

D. The Groups of Asserted Claims

The asserted claims across the seven patents-in-suit share characteristics and limitations. Complainant Align placed them into four groups for the purpose of analyzing the threshold issues of violation, *e.g.*, whether there is an imported "article," and whether the territorial requirements of violation have been met. Align's Response to Respondents' Petition for Review ("Align Pet.") at 4-5. Some claims are in more than one group. There was no objection raised to the use of these groupings.¹⁴

¹⁴ See Respondents' Response to the Notice of the Commission's Determination to Review the Final Initial Determination of the Administrative Law Judge ("Resps. Sub."); Response of the Office of Unfair Import Investigations to the Commission's Request for Written Submissions on Issues Under Review ("IA Sub.");

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1. Group I

The Group I claims (Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent) are directed to a method of forming dental appliances starting with a digital data set.

2. Group II

The Group II claims (Claims 31 and 32 of the '325 patent; claims 1 and 4-8 of the '863 patent; claims 1, 3, 7 and 9 of the '666 patent; and claims 1, 3 and 5 of the '487 patent) are directed to methods of producing digital data sets.

3. Group III

The Group III claims (Claims 7-9 of the '487 patent) are directed to a treatment plan (*i.e.*, a series of digital data sets) on a storage medium.

4. Group IV

The Group IV claims (Claims 1, 2, 3, 11, 13, 14, 21, 30, 31, 32, 33, 34, 35, 38, 39 of the '325 patent; claims 1 and 3 of the '880 patent; claims 1 of the '511 patent; and claims 1, 2, 38, 39, 41, and 62 of the '874 patent) are directed to methods of producing dental appliances.

E. The Accused Products and Processes

1. Accused Products

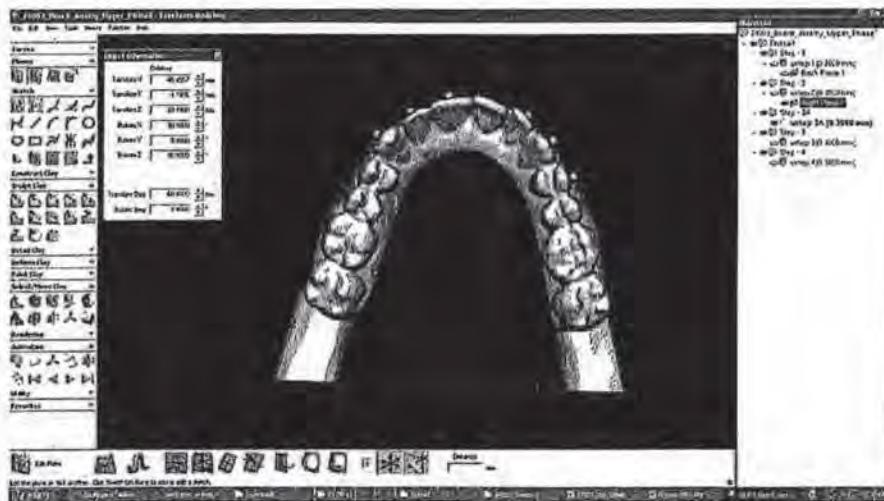
Align accuses digital data sets made by CCUS and CCPK and the customized sequential dental positioning appliances made therefrom for the purpose of orthodontic treatment.

Respondents' Reply To The OUII & Align's Response To Notice Of The Commission's Determination To Review The Final Initial Determination Of The ALJ And Exhibits ("Resps. Reply Sub."); Response of the Office of Unfair Import Investigations to Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding ("IA Reply Sub.").

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The ALJ found the accused products to be digital models, digital data, and treatment plans, expressed as digital data sets, which are virtual three-dimensional models of the desired position of patients' teeth at various stages of orthodontic treatment. The models are initially created based on impressions of patients' teeth. The models are manipulated in Pakistan by CCPK, as set forth below, and transmitted to CCUS. ID at 21-22. The digital models, digital data, and treatment plans are electronically transmitted by uploading them (a CCPK technician in Pakistan electronically transmits the digital data to CCUS's server for CCUS use in the United States). ID at 21-22; Tr. at 316-17; CX-1150C at Qs. 92-145; Tr. at 168:14-170:11, 170:18-173:24, and 177:2-193:6; Tr. at 312:20-322:12; Tr. at 442:5-443:10. The digital models are subsequently used to print 3-D physical models of a patient's teeth. *Id.* The aligners, *i.e.*, the incremental dental positioning adjustment appliances, are formed over the physical models of the teeth. *Id.*

Below is an image of a computer model of the teeth.



CX-90C at 54.

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Below is a picture of a physical model of teeth.



CX-875C. CCUS forms aligners by thermoplastic molding over a physical model of the teeth. Tr. at 318:4-7.

2. Accused Processes

As set forth below, the ALJ found the process implemented by CCPK and CCUS to produce the digital data sets and subsequent dental positioning adjustment appliances to constitute the “accused process.” CCUS performs certain steps in the United States and CCPK performs certain steps in Pakistan. *See* ID at 472-73.

a. Scanning stone models into a digital model: Employees of CCUS and CCPK testified that CCUS creates digital data sets by scanning stone models of a patient’s dental impressions, which represent the patient’s initial tooth arrangement. ID at 472 (citing Tr. at 171:8-11; 314:19-315:18).

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b. and c. Transmission of initial digital data sets (from Texas to Pakistan)

and software conversion: CCUS uploads the 3D digital scan to a server for CCPK to access. ID at 698. CCPK imports the scan data into FreeForm, which is a 3D modeling software program, to prepare the initial digital data set. *Id.*

d. Sectioning: Mr. Pumphrey, an employee of CCUS, testified that CCPK sections the initial digital data sets representing the initial position of teeth for the upper and lower jaws into 16 separate teeth. Tr. at 330:11-331:5. The ALJ found that this sectioning, depicted in CX-889C, shows that the sectioning defines boundaries about the individual teeth. ID at 484 (citing Tr. at 330:13-331:5; CX-889C).

e. [[

]]

f. [[

]]

g. Transmission of treatment setup to professional for approval: Mr. Arif testified that a copy of the “treatment setup” is transmitted to CCUS, which then sends the “treatment setup” to the dentist for approval. ID at 689; Tr. at 172:10-172:14; 335:1-

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13; 335:19-336:2. Transmission occurs when CCPK uploads the setup to the CCUS server. Tr. at 316:4-8.

h. Stepping process (interpolation and festooning): If the dentist in the United States approves the planned model of the final position, CCPK proceeds to the “stepping process,” which consists of creating steps, or intermediate tooth positions, that move the teeth from their initial position to the final position. Tr. at 172:15-173:13. The ALJ found that the CCPK technicians use the “Generate Steps” function of the FreeForm software to generate a set of stepped locations for a tooth between two tooth positions. ID at 495 (citing Tr. at 336:11-337:9; *see also* CX-1150C at Q. 198). The ALJ found that the text in the FreeForm software regarding the “Generate Steps” function states that “[s]teps will be generated automatically by interpolating between the positions of the corresponding pieces in the starting and ending folders.” *Id.* (citing CX-107C at 5:33). The operator also cleans up the models of the teeth through a process known as “festooning” after the computer has performed the interpolation. Tr. at 339:23-341:5.

i. and j. Uploading of digital data sets []

]]: CCPK electronically transmits the digital data sets to CCUS by uploading them onto the CCUS server. Tr. at 316:12-22; 341:14-17. [[

]]

PUBLIC VERSION**II. STANDARD FOR DETERMINATION ON REVIEW**

Once the Commission has determined to review the decision of the ALJ, the agency has all of the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. 5 U.S.C. § 557(b); *Certain Acid-Washed Garments and Accessories*, Inv. No. 337-TA-324, Comm'n Op. at 4-5 (Aug. 6, 1992). Commission Rule 210.45(c) implements 5 U.S.C. § 557(b). In other words, once the Commission decides to review the decision of the ALJ, the Commission may conduct a review of the findings of fact and conclusions of law presented by the record under a *de novo* standard.

III. DISCUSSION**A. “Importation . . . of Articles”**

There is a threshold issue that relates to all of the patent claims asserted, *i.e.*, whether Respondents’ electronic transmissions of digital data sets constitute “importation of . . . articles” within the meaning of Section 337.

In their petition for review, Respondents argue that the digital data sets representing the initial, intermediate, and final positions of patients’ teeth are not “articles” within the meaning of Section 337(a)(1)(B), and therefore cannot be the basis of any unfair act under the statute. Resp. Pet. at 66-67. Moreover, Respondents contend that because the accused data sets are brought into the United States by CCPK by uploading them to CCUS’s server in Houston, Texas, this mode of bringing the accused products into the United States is not an importation into the United States as anticipated by Section 337(a)(1)(B). *Id.* at 67. Align and the IA oppose Respondents’ position,

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arguing that the ALJ correctly found that the language of the statute and its legislative history indicate that the term “articles” includes within its meaning the accused products.

The Commission affirms the ALJ’s finding that the accused products are “articles” within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

1. The ID

The ALJ found that the accused digital data sets are “articles” within the scope of the Commission’s “jurisdiction,” although he acknowledged that the issue is not necessarily jurisdictional and that he was only treating the issue as one of jurisdiction because the parties had raised the issue in that manner. ID at 17 and n.1 (discussing *Certain Drill Bits and Products Containing Same*, Inv. No. 337-TA-844, Comm’n Notice (August 22, 2012) (not adopting statement in ID that issue was jurisdictional)). The ALJ found that *Hardware Logic* is directly on point. *Id.* at 18 (discussing *Certain Hardware Logic*, Inv. No. 337-TA-383). The ALJ noted that in *Hardware Logic*, the Commission rejected the argument that software is not an “article” and that remedial orders could not reach energy, which is intangible. *Id.* (citing *Hardware Logic*, Comm’n Op. at 18, fn. 84 (Dec. 1994)). The ALJ observed that the Commission issued a cease and desist order in *Hardware Logic* that prohibited, *inter alia*, “the importation (including via electronic transmission), sale, offer for sale, lease, loan, other transfer, duplication, or distribution (including electronic distribution) of imported software and other components that contributorily infringe the patents in issue.” *Id.* (citing *Hardware Logic* Comm’n Op. at 21).

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The ALJ stated that this understanding of *Hardware Logic* is confirmed by the Commission's Opinion in Investigation No. 337-TA-562 (Enforcement), where the Commission cited *Hardware Logic* to hold that "it has jurisdiction and authority to reach digital data electronically transmitted to a recipient in the United States," before finding that the consent order did not expressly prohibit electronic transmissions. *Id.* at 7.

The ALJ rejected Respondents' argument that the Federal Circuit opinion in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367 (Fed. Cir. 2003), stated that Section 337 does not cover information because the court in *Bayer AG* was addressing the issue of whether or not 35 U.S.C. § 271(g) applied to claims directed to methods of use rather than methods of manufacture.¹⁵ *Id.* at 19 (discussing *Bayer*, 340 F.3d at 1371). The ALJ concluded that any discussion in *Bayer* regarding the scope of 19 U.S.C. § 1337 was dicta and is not controlling, and that in any case, the Federal Circuit acknowledged that the scope of 19 U.S.C. § 1337 may be broader than 271(g). *Id.*

The ALJ also rejected Respondents' argument that the Federal Circuit stated in *Nuijten* that an "article" must be tangible because that case addressed the specific question of whether certain claims directed to a "signal" were invalid as being directed to non-statutory subject matter under 35 U.S.C. § 101. *Id.* at 20 (citing *In re Nuijten*, 500 F.3d 1346, 1348 (Fed. Cir. 2007)).

¹⁵ The Federal Circuit in *Bayer* stated:

We recognize that section 1337 covers both articles that were "made" and articles that were "produced, processed, or mined." While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Bayer AG, 340 F.3d at 1374 n.9.

PUBLIC VERSION**2. Arguments¹⁶**

Respondents argue that neither the plain language of Section 337 nor its legislative history provide a basis for interpreting intangible, electronic transmissions as “articles.” Resp. Submission at 2. Respondents assert that the Federal Circuit has already concluded that the legislative history and language of Section 337 limit “articles” to tangible items. Respondents assert that the Court concluded that “product” in § 271(g) is the same as “articles” described in Section 337. *Id.* at 2-3 (quoting *Bayer*, 340 F.3d at 1373).

Respondents argue that it is clear from the debate that led to the enactment of the Tariff Act of 1930 that members of both houses equated “articles” with tangible items, often using the term “articles” synonymously with “goods,” “merchandise,” and “commodities.” *Id.* Respondents state that Section 337 has been amended a dozen times, but none of these amendments suggest any Congressional intent to change its long-standing interpretation of “articles” from something tangible. *Id.* at 6-7. Respondents argue that, in other legislation, Congress explicitly exempted telecommunications from tariff duties and concludes that this is express evidence of Congress’s intent not to regulate the entry of digital information through telecommunications transmission. *Id.*

Respondents argue that the Commission’s order in *Hardware Logic* does not hold that electronic transmission is an “importation” or that digital data is an “article.” *Id.* at 10. Respondents assert that the “software” component described in the Recommended Determination (“RD”) was stored on a cartridge tape and was imported only one time, on

¹⁶ The Commission fully considered the submissions of the parties and of the public third-party submitters. The full submissions are available on the Commission website at <https://edis.usitc.gov>.

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August 2, 1996. *Id.* (citing RD at 6, 202). Respondents assert that “nowhere in the RD or cease and desist order did the Commission hold that the possible electronic transmission of that software was an importation of an article under the statute. Nor did it hold that the electronic data itself was an ‘article.’” *Id.*

Respondents argue that the Commission’s ability to protect domestic patents and copyrights would not be “eviscerated” if “articles” doesn’t include electronic transmissions because patent and copyright holders will have remedies elsewhere, and the Federal Circuit rejected a similar argument in *Bayer* when it construed the scope of § 271(g). *Id.* at 2

Respondents note Align’s proposed definition of “articles” as “units of commerce,” and argue that there is no evidence that the electronic transmissions are sold as “units of commerce.” Resps. Add. Sub. at 6. Respondents state that “[i]t is clear that CCUS paid CCPK for its services rendered in total and was not paid for “units.” *Id.*

Respondents contest Align’s reliance on two district court decisions, *CNET* and *Ormco*. *Id.* at 3. Respondents assert that *CNET* is simply the denial of defendant’s motion for summary judgment, involved § 271(g), and is distinguishable on its facts because in *CNET* the electronic catalog is bought and sold while in the instant case there is no record evidence that the computer files are bought and sold. *Id.* at 3-4.

Respondents assert that *Ormco*’s holding that no product was required to be sold under § 271(g) is undercut by the Federal Circuit’s holding that such a sold product is required under § 271(c) in *PharmaStem Therapeutics, Inc. v. ViaCell*, 491 F.3d 1342, 1357-58 (Fed. Cir. 2007)).

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Align argues that electronic transmission of data constitutes “importation” of “articles” under Section 337. Align Sub. at 1. Align suggests that the text, legislative history, and overall purpose of Section 337 support the conclusion that the term “articles” encompasses any identifiable unit of commercial value, including electronically transmitted data. *Id.* at 1-2. Align asserts that the Commission has interpreted “importation” of “articles” accordingly in *Hardware Logic* and in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562. *Id.* at 2. Align quotes the Commission Opinion in the latter case that “it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States,” and states that this is a conclusion equally applicable to determinations of violation and subsequent remedy. *Id.*

Align cites dictionary definitions to support its position. *Id.* at 3. Align further contends that the broad meaning of the term “articles” is set by Section 337 itself, and that its title (“Unfair practices in import trade”) and its terms reflect a concern regarding commercial practices. *Id.* Complainant argues that the accompanying terms “sale for importation,” “importation,” and “sale after importation,” indicate that Congress meant all units of commercial value -- items that can be bought, sold, or otherwise transferred. Align concludes that this is consistent with other courts’ findings that digital data is an “article of commerce.” *Id.* at 4. Align argues that Congress intended “article” to encompass anything that infringes, and that limiting “articles” to physical objects would arbitrarily exclude a broad range of infringing products and severely limit the ability of this agency to perform its intended function. *Id.* at 4-5. Align states that a remedial

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statute should be “construed broadly to effectuate its purposes,” and suggests that Section 337 is such a remedial statute. *Id.* at 7.

Align asserts that “[e]xempting electronically transmitted data from Section 337(a)(1)(B) would eviscerate the Commission’s ability to protect the domestic recording, entertainment, publishing, and software industries from copyright infringement by downloadable books, movies, television programs, software, and music.” *Id.* at 7. Align also suggests that new three-dimensional printers could allow importers to switch from the importation of physical products to the electronic transmission of designs for these products. *Id.*

Align notes that, in issuing a cease and desist order in *Hardware Logic*, the Commission relied on the legislative history of Section 337 and the statutory mandate to ensure adequate protection of U.S. intellectual property rights, and found that coverage of electronic transmissions was necessary in order to make the order fully effective. *Id.* at 10.

Align argues that its view is supported by the conclusions of other courts and agencies. *Id.* at 11. Align points to a statement by the Supreme Court that “[i]f there be actual bringing in [to the United States] it is importation ***regardless of the mode in which it is effected.***” *Id.* at 8 (quoting *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) (emphasis in brief)). Align points to a Customs ruling that “the transmission of software modules and products to the United States from a foreign country via the Internet is an importation of merchandise into the customs territory of the United States in that the software modules and products are brought into the United States from a foreign country.” *Id.* at 11-12 (quoting Customs Ruling HQ 114459 (Sept. 17, 1998)). Align

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similarly points to a series of Court of International Trade (“CIT”) decisions interpreting Section 222 of the Trade Act of 1974, 19 U.S.C. § 2272, in which the CIT refused to read a tangibility requirement into the statute. *Id.* at 12 (citing, *inter alia*, *Computer Scis. Corp v. Sec'y of Labor.*, 414 F. Supp.2d at 1340-41 (CIT 2006)). Align argues that the Trade Act of 1974 was an outgrowth of the Tariff Act of 1930 and that when Congress uses the same language in two statutes having the same purposes, it is appropriate to presume that Congress intended the text to have the same meaning in both statutes. *Id.* at 12-13 (citing *Smith v. City of Jackson*, 544 U.S. 228, 233 (2005)).

Align distinguishes *Bayer*, stating that the product in *Bayer* was “information in the abstract,” specifically, “the knowledge that a substance possesses a particular quality,” which is not the result of practicing a patented process. *Id.* at 3. Align states that in *CNET*, the court found that an electronic catalogue, maintained as a data file and downloaded, is a product under section 271(g). *Id.*

The IA also argues that “articles” includes electronic transmissions. The IA highlights a statement from the Commission Opinion on Remedy in *Hardware Logic*, and argues that this statement would be accorded deference by the Federal Circuit under *Chevron*: “We do not think the legislative history of Section 337 precludes coverage of electronically transmitted software; in fact, we believe that it supports the conclusion that such coverage is proper.” IA Reply Sub. at 4 (quoting *Hardware Logic*, Commission Opinion on Remedy, the Public Interest, and Bonding at 28 (April 1, 1998); citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984)). The IA argues that *Hardware Logic* necessarily supports the conclusion that electronic transmission of data is importation for purposes of violation, and that this was confirmed

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recently by *Dental Appliances*, Inv. No. 337-TA-562 (Enforcement). *Id.*; IA Add. Reply Sub. at 4.

The IA further agrees with the MPAA that the Commission's practice of exercising jurisdiction over electronically imported articles is mandated by Supreme Court precedent, specifically *Cunard* and *Canton Railroad*, because importation occurs regardless of the mode an article is brought into the country. IA Add. Reply Sub. at 2-3. The IA counters Google and Katz's reliance on *Nuitjen*, *Bayer*, *NTP*, *Microsoft*, and *Suprema*, arguing that *Nuitjen* is directed to an issue of patentability under § 101, *Bayer* and *NTP* were directed to the scope of § 271(g), *Microsoft* was directed to the scope of § 271(f), and *Suprema* was directed to the scope of § 271(b) not § 271(c). *Id.* (discussing *Suprema, Inc. v. ITC*, 742 F.3d 1350 (Fed. Cir. 2013); *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007); *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007)).

Third-Party Submitter Motion Picture Association of America, Inc. ("MPAA") states that physical media are being replaced by electronic, downloadable formats. MPAA Sub. at 2. The MPAA asserts that infringement is also shifting to downloadable formats, leading to a loss of \$58 billion annually, including 373,000 jobs, \$16 billion in lost employee earnings, and \$3 billion in tax revenue. *Id.*

The MPAA states that the legislative history of Section 337 demonstrates that Congress intended for the Commission to have very broad jurisdiction over unfair acts in international trade. *Id.* at 11. The MPAA argues that the Commission has a longstanding

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practice, affirmed by the Federal Circuit, of taking a flexible approach to its jurisdiction and authority, reflecting the “realities of the marketplace.” *Id.* at 11-12.

The MPAA argues that the Federal Circuit’s decisions in *Suprema* and *Bayer* were related to narrow patent issues and do not bear on whether imported electronic transmissions can constitute “articles” for purposes of Section 337. *Id.* at 13.

The MPAA asserts that the remedy provisions of Section 337 do not dictate that “articles” be limited to physical objects because Section 337 also gives the Commission authority to issue cease and desist orders, and that cease and desist orders need not be limited to the situation where they aid enforcement of exclusion orders or are issued in lieu of exclusion orders. *Id.* at 3-4.

The MPAA draws a different conclusion than Google about the absence of a specific discussion of electronic transmissions in the legislative history, stating that “the technological state of affairs at the time the statute was drafted does not lock in historical amber the meaning of a general term such as the word ‘articles.’” *Id.* The MPAA instead cites *Diamond v. Chakrabarty* for the proposition that a statute is not to be confined to the particular applications contemplated by the legislators, and argues that statutory silence cannot be interpreted as lack of coverage. *Id.* at 5-6 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980)).

The MPAA argues that the Commission’s established practice regarding its authority over electronic articles is consistent with U.S. government policy. *Id.* at 8.

Third-Party Submitter Andrew Katz asserts that Federal Circuit case law strongly suggests that electronic transmissions are not articles under either Section 337(a)(1)(B)(i) or (ii) because they are intangible. Katz Sub. at 2.

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Mr. Katz states that the article in § 271(a) is the “patented invention” and that a patented invention is one within the statutory classes of patentable subject matter in 35 U.S.C. § 101. *Id.* at 3. Mr. Katz reasons that electronic transmissions cannot be patentable inventions under *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007), and therefore cannot be directly infringing articles under Section 337(a)(1)(B)(i). *Id.* at 2, 11. Mr. Katz further asserts that the case law, including *Microsoft*, suggests that an article for purposes of § 271(c) must also be a tangible product. *Id.* at 4.

Mr. Katz submits that the Commission should be guided by § 271 in deciding the meaning of “article” for purposes of Section 337 because the Federal Circuit in *Suprema* indicated that the infringement provisions of Section 337 must be interpreted to be consistent with, and limited by, the court’s jurisprudence under 35 U.S.C. § 271. *Id.*

Mr. Katz argues that the Commission’s opinion in *Hardware Logic* has been displaced by the Federal Circuit’s decisions in *Suprema* and *Bayer* and the Supreme Court’s decision in *Microsoft*. *Id.* at 12-13.

Third-Party Submitter Google submits that, as a matter of law and policy, the Commission is not an appropriate forum for software patent litigation if the accused products are non-tangible electronic transmissions into the United States. Google Sub. at 2.

Google submits that the Commission has recognized the limits of its jurisdiction and remedial powers when it observed that it is a creature of statute and that its authority must be found in its enabling statute. *Id.* at 2. Google argues that the *Electronic Devices* investigation stands for the proposition that Section 337 does not apply to all instances of infringement of a U.S. patent, even with a nexus to importation, because infringement

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must apply to the “articles as imported.” *Id.* at 2-3 (citing *Electronic Devices*, Comm’n Op. at 14, 19).

Google points out that the Commission recently reinforced the “finding of actual ‘articles protected’ even with respect to licensing-based domestic industries.” *Id.* at 6 (citing *Certain Computers and Computer Peripheral Devices, and Components Thereof*, and Products Containing Same, Inv. No. 337-TA-841, Comm’n Op. at 32 (Jan. 9, 2014) (“There is an ‘articles’ requirement for subparagraph (C), in addition to (A) and (B).”)) Google further argues that exclusion orders under Section 337(d)(1) and seizure and forfeiture orders, under Section 337(i), cannot apply to electronic transmissions. *Id.* at 6.

Google argues that *Hardware Logic* did not consider the full legislative history and was incorrectly decided. *Id.* at 7.

Google further argues that “it would fly in the face of Section 337” to issue cease and desist orders directed at electronic transmissions when cease and desist orders were intended to aid the enforcement of exclusion orders. *Id.* at 14. Google states that regulation of electronic transmissions by the Commission should be left for Congress to decide. *Id.*

Third-Party Submitter Association of American Publishers (“AAP”) submitted a reply submission, endorsing the comments submitted by the MPAA and taking the position that “electronic transmissions” are “articles” within the meaning of Section 337. AAP Reply Sub. at 1. The AAP submits that this topic is of critical concern to the U.S. publishing industry, which produces and trades millions of eBooks around the world annually. *Id.* The AAP states that today, software, books, movies, music, and games are increasingly transmitted to consumers in machine-readable form by electronic means

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such as eBooks, mp3s, etc. *Id.* The AAP argues that the need for the Commission to provide a remedy for eBooks is greater than the need to provide a remedy for physical books. *Id.*

The AAP argues that Congress has consistently intended “the primary purpose of section 337 . . . to be a trade statute to prevent unfair practice through importation of goods.” *Id.* at 2 (quoting Google Sub. at 4). The AAP suggests that Congress has left the term “articles” undefined in order to ensure that the language of Section 337 remains broad enough to prevent all types of unfair practice. *Id.* at 2-3.

The AAP argues that trade includes digital trade, which includes products and services delivered via the internet. *Id.* at 3. In reaching this understanding, the AAP relies on the Commission’s definition of digital trade in its report “Digital Trade in the U.S. and Global Economies, Part 1.” *Id.* at 3.

Third-Party Submitter Nokia argues that *Bayer* does not establish that electronic transmissions are not articles under Section 337. Nokia argues that the court’s discussion of Section 337 was dicta, that it relates to Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i), and that electronic transmission of software that can be read and combined by a device is much more than intangible information. Nokia Sub. at 8.

Nokia argues that electronic transmissions are within the Commission’s remedial authority, and that the Commission has broad discretion in selecting the form, scope, and extent of the remedy. *Id.* at 8-9. Nokia argues that if a violator attempts to circumvent an exclusion order, then Section 337(f) authorizes the Commission to order the violator to cease and desist. *Id.* at 9.

3. Analysis

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In this investigation, Align's infringement claims concern respondents' digital datasets and treatment plans representing the initial, intermediate, and final positions of patients' teeth for use in fabricating dental appliances for orthodontic treatment of individual patients.¹⁷ The Commission therefore must determine whether the phrase "importation ... of articles" as used in Section 337(a)(1)(B) encompasses these digital data sets that are electronically transmitted into the United States.

The Commission affirms the ALJ's conclusion that the accused products are "articles" within the meaning of Section 337(a)(1)(B) and that the mode of bringing the accused products into the United States constitutes importation of the accused products into the United States pursuant to Section 337(a)(1)(B).

The parties' arguments revolve around the specific authority conferred upon the Commission to investigate and determine whether a violation of Section 337 has occurred by the importation or sale of infringing articles in the United States pursuant to Section 337(a)(1)(B). The language of Section 337(a)(1)(B)(i) and (ii) at issue here provides:

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

...
(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

¹⁷ Align disputes that the accused products are intangible, noting that the digital data sets at issue here are physical articles whether they are stored on a physical medium, *i.e.*, a physical server or hard drive, or transmitted in between storage media. Align Sub. at 1 n.2. Further, Align argues that the act of importation into the United States from Pakistan is not complete until the entire treatment plan is saved on a U.S.-based server. Align Sub. on Issues Under Review at 7 n.9.

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(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

The phrase “importation . . . of articles” appears in the introductory text of Section 337(a)(1)(B) and applies to both Section 337(a)(1)(B)(i) and (ii), which define a violation by reason of articles that infringe a valid and enforceable U.S. patent or that are “made, produced, processed or mined under, or by means of” a valid and enforceable process patent. The same language is used in defining a violation of Section 337 by reference to infringement of a valid and enforceable registered U.S. copyright, a valid and enforceable registered U.S. trademark, and a vessel design protected by chapter 13 of Title 17. See 19 U.S.C. § 1337(a)(1)(B), (C), and (E).¹⁸ The Commission sought briefing from the parties and the public in order to address respondents’ arguments concerning whether the statutory term “importation . . . of articles” may encompass the respondents’ digital data sets that are electronically transmitted into the United States.¹⁹ 78 Fed. Reg. 46611 (Aug. 1, 2013); 79 Fed. Reg. 4174 (Jan. 24, 2014).

¹⁸ Section 337(a)(1)(D), which relates to a registered semiconductor mask work, does not use the term “article.” 19 U.S.C. § 1337(a)(1)(D).

¹⁹ Commenters dispute whether the Commission decided this issue in *Hardware Logic* and whether it held that electronic transmissions are “articles” within the meaning of Section 337 for purposes of violation in *Hardware Logic* and subsequent determinations. In *Hardware Logic*, the products at issue were hardware logic emulation systems consisting of reconfigurable logic devices and interconnect resources that were programmed primarily via software to emulate an integrated circuit design. *Certain Hardware Logic Systems and Components Thereof (“Hardware Logic”)*, Inv. No. 337-TA-383, Initial Determination, 1997 WL 665006 at *8 (July 31, 1997). The ALJ found that software contributorily infringed certain asserted claims, including method claims. *Id.* at *92-*98. See also Comm’n Op. at 27. In so ruling, the ALJ found that the software components were electronically transmitted to the United States in some instances. *Id.* at * 95. With regard to importation, the ALJ found that the importation requirement was met by undisputed evidence of respondents’ importation of logic boards and components such as software, and that even if he were to accept respondents’ argument regarding electronic transmission of software, respondents had also imported software on a cartridge tape on at least one occasion. ID at 6. In the RD, the ALJ, referring to the Commission’s broad remedial authority to fashion a remedy once it finds a violation, found that “there is a direct nexus between respondents’ importation, via electronic transmission or otherwise, and infringement of the patents in issue,” and recommended an exclusion order and cease and desist order prohibiting infringing imports, including electronic transmissions. RD at 197. Noting that “the Commission has the

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We acknowledge that the construction of the term “articles” is a difficult question in part because the term “articles” is not expressly defined in the statute. The term “articles” in connection with unfairly traded imports originated in the 1922 Tariff Act and was re-enacted in the Tariff Act of 1930 at a time when internet downloads were not in existence. We have carefully examined the arguments of the parties and the third-party submitters on this issue. On balance, the Commission concludes that the statutory construction of “articles” that hews most closely to the language of the statute and implements the avowed Congressional purpose of Section 337 encompasses within its scope the electronic transmission of the digital data sets at issue in this investigation.

legal authority to cover electronic importations,” the Commission issued a cease and desist order including electronically transmitted software within its scope. *Hardware Logic*, Comm’n Op. on Remedy, the Public Interest, and Bonding, 1998 WL 307240 at *1 (March 1998). The Commission also issued an exclusion order, but declined to extend the scope to cover electronic transmissions deferring to Customs’ enforcement position. *Id.* at *11, *15.

In *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, respondent Fortinet’s accused products were an encased combination of hardware and software. Final ID at 57 (May 9, 2005). The parties stipulated that at least certain hardware components were imported and either included the software or had the software installed in the United States after electronic transmission of the software to Fortinet’s U.S. facility. The Commission determined not to review the ALJ’s finding of violation, Notice, 70 Fed. Reg. 40731 (July 14, 2005). Consistent with *Hardware Logic*, the Commission included electronic transmissions in the cease and desist order but not the exclusion order. Comm’n Op. at 4-5 (August 23, 2005).

In *Certain Set Top Boxes and Components Thereof*, Inv. No. 337-TA-454, the accused products were hardware devices with software. The ALJ recommended an exclusion order covering software, RD at 306 (June 21, 2002), but the Commission determined not to review the ALJ’s finding of no violation and therefore did not reach the issue of remedy. Notice, 67 Fed. Reg. 56856 (Sept. 5, 2002). The RD is a recommendation and has no legal effect itself. *See Key v. Sullivan*, 925 F.2d 1056 (7th Cir. 1991).

In *Certain Machine Vision Software, Mach. Vision Systems*, Inv. No. 337-TA-680, the ALJ found importation based on electronic transmission of software. Both the final ID and the Commission found no violation of Section 337. *See* ID at 96; Commission Notice, 75 Fed. Reg. 71146 (Nov. 22, 2010) (modifying the ID and finding no violation of Section 337 based on invalidity under 35 U.S.C. § 101). The ALJ noted in the ID that it was not disputed that the importation requirement may be satisfied by electronic transmission based on *Hardware Logic*, ID at 8 and n.2. The only importation issue in the final ID was with regard to Resolution Technology and Visics. They argued that they obtained their products from MVTEC in the United States. But MVTEC had been found to import in Order No. 60, so Resolution Technology and Visics were found to “sell after importation.” It is unclear from Order No. 60 (and thus unclear from the ID) whether the ALJ relied on electronic transmission for importation.

Most recently in the related proceeding, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Public Comm’n Op. (Feb. 19, 2013), the Commission held that the scope of its cease and desist orders and consent orders can cover electronic transmissions when explicitly recited in those orders. That proceeding did not address whether electronic transmissions of digital data are articles in the context of violation.

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The statute was drafted with broad language that encompasses imports that infringe the major forms of intellectual property rights – patent, trademark, and copyright – as well as other forms of unfair acts and methods of competition. Moreover, each time the statute has been amended, the legislative history has stated that the legislative purpose is to prevent every type of unfair act in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest) and to strengthen protection of intellectual property rights. To faithfully carry out the clear purpose of the statute in accordance with Congress's intent, the Commission concludes that "articles" cannot be limited in the manner argued by the respondents.

Our analysis begins with the language of the statute. *Perrin v. United States*, 444 U.S. 37, 42 (1979). The term "articles" in connection with unfair acts relating to imports first appeared in Section 316 of the 1922 Tariff Act, which was the predecessor to Section 337 of the Tariff Act of 1930. The 1922 Act provided remedies against unfair methods of competition and unfair acts in connection with articles imported or sold in the United States. This provision was re-enacted with some modifications in 1930. With each subsequent amendment, the term "articles" was retained in the statutory provisions circumscribing unfair acts in connection with importation.

"Articles" is not explicitly defined within Section 337. Notably, there are no statutory words of limitation used in conjunction with "articles" in Section 337 that would restrict the category, type, or form of imports that are covered by the scope of "articles" subject to Section 337. The fact that Congress did not place express restrictions limiting the scope of "articles" to any particular type or form is instructive as to the meaning of this term. *See generally* 2A Singer, Sutherland Statutory Construction

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§ 47.38 (7th ed. 2007) (“In construing a statute, it is always safer not to add or to subtract from the language of the statute unless imperatively required to make it a rational statute.”); *62 Cases of Jam v. United States*, 340 U.S. 593, 596 (1951) (in statutory construction, the court’s role “is . . . to ascertain – neither to add nor to subtract, neither to delete nor to distort”). Likewise, the statutory language at issue here does not encompass some infringing importations while excluding others. *See United States v. Simpson*, 252 U.S. 465, 466-67 (1920) (refusing to confine the meaning of “transported” to be limited to transportation for hire or by public carriers and thereby exclude transportation by automobile).

Consistent with these authorities, the Commission, having examined the identical statutory language at issue here, has previously refused to impose limitations upon the term “articles” that were not mandated by this statutory language. *See Certain Sputtered Carbon Coated Computer Disks and Products Containing Same, Including Disk Drives*, Inv. No. 337-TA-350, USITC Pub. 2701, Comm’n Op. at 4-10 (Nov. 1993) (rejecting respondents’ proposed construction of “articles” as restricted to “articles of foreign manufacture” because the statutory term “articles” contained no such restriction). In so doing, the Commission stated that “it is not appropriate for the Commission to insert into the statute jurisdictional limitations not placed there by Congress.” *Id.* at 5. Thus, the Commission finds that the statutory language does not circumscribe the category of items that fall within the scope of articles. It appears to broadly cover infringing imports, without express limitation as to form or type of said articles.

To further ascertain the Congressionally intended scope of “articles,” it is helpful to look to contemporaneous dictionaries to understand the plain and ordinary meaning of

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“article” at the time of enactment. *See FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (looking to dictionary definition); *Hibbs v. Winn*, 542 U.S. 88, 117 (2004) (contemporaneous dictionary is the relevant dictionary).

Contemporaneous definitions of “article” embrace a generic meaning that is synonymous with a particular item or thing, such as a unit of merchandise.²⁰ A 1924 edition of Webster’s, which uses the 1909 edition’s typesetting, defines “article,” in pertinent part, as “Something considered by itself and as apart from other things of the same kind or from the whole of which it forms a part; also, a thing of a particular class or kind; as, an article of merchandise; salt is a necessary article.” Harris, WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE at 131, G. & C. Merriam Co. (1924).²¹ Thus, the term “article” was understood at the time of the enactment of the Tariff Act to carry the meaning of an identifiable unit, item, or thing, with examples indicating that such articles may be traded in commerce or used by consumers.

Another common definition of the term “article” is a piece of writing included with others in a newspaper, magazine, or other publication. *See, e.g.*, Funk, NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE, Funk & Wagnalls Co. at 162 (1929)

²⁰ Some definitions of “article,” in addition to stating a broader generic meaning, also set forth a more granular meaning of a material thing. For example, a 1929 edition of Funk and Wagnalls defines “article,” in pertinent part, as: “A particular object or substance; a material thing or class of things; as, an article of food.” Funk, NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE, Funk & Wagnalls Co. at 162 (1929). The Federal Circuit, interpreting 35 U.S.C. § 271(g), noted one definition of “article” in Webster’s Third New International Dictionary (a more recent edition of Webster’s). “Article” is there defined as “one of a class of material things . . . pieces of goods; COMMODITY.” *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003). Thus, while an “article” was understood to include something material, as shown in the text above, the term was also understood to embrace a broader meaning that describes something that is traded in commerce.

²¹ More recent context relevant definitions of “articles” are in accord. *See, e.g.*, WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY (2002) (“5: a material thing”; ... “6a: a thing of a particular class or kind as distinct from a thing of another class of kind”); RANDOM HOUSE WEBSTER’S UNABRIDGED DICTIONARY (2nd Edition 2001) (“2. An individual object, member, or portion of a class; an item or particular; an article of food; articles of clothing; ... 4. An item for sale; commodity”).

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(providing an alternate definition of “article” as “A brief composition, as in a serial publication; an essay; a paper; as, an *article* in the morning daily.”); Harris, WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE at 131, G. & C. Merriam Co. (1924) (also defining “article” as “A literary composition forming an independent portion of a magazine, newspaper, or cyclopedia, etc.”). Courts have long recognized various unfair competition causes of action for misappropriation when such literary works (articles) are electronically transmitted, including when the gravamen of the cause of action is the mere data contained within a broader arrangement of literary work.. *See, e.g., International News Service v Associated Press*, 248 US 215, 234 (1918) (misappropriation of “fresh” news within “news articles”) (citing *Board of Trade v. Christie Grain & Stock*, 198 US 236 (1905) (wrongful appropriation of price quotes), and *National Tel. News Co. v. Western Union Tel. Co.*, 119 F. 294 (7th Cir. 1902) (injurious appropriation of news sent by telegraph before printing on ticker tape)).

The meaning of “articles” must also be interpreted in the context in which it appears in the statute. *Dolan v. United States Postal Service*, 546 U.S. 481, 486 (2006). In the statutory provisions defining a violation of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), “articles” appears in conjunction with the terms “importation” and “sale,” indicating that articles subject to the statute are imported items that are bought and sold in commerce. Pertinent to the present inquiry, both the Supreme Court and appellate courts have held that digital files are “articles of commerce.” *Reno v. Condon* 528 U.S. 141, 148 (2000) (“Because drivers’ information is, in this context, an article of commerce, its sale or release into the interstate stream of business is sufficient to support congressional regulation.”); *Senne v. Vill. Of Palatine*, 695 F.3d 617, 620 (7th

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Cir. 2012) (“Notably, *Reno* does not appear to rely on the *sale* of any information. Instead, it identifies the information that the state possesses and ‘release[s]’ into interstate commerce as ‘an article of commerce.’”) (emphasis in original). Further, with respect to importation, the Supreme Court explained in *Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923) that importation “consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode by which it is effected.” *See also Canton Railroad Co. v. Rogan*, 340 U.S. 511, 515 (1951) (“to import means to bring into the country”). Accordingly, based on the juxtaposition of the term “articles” in relation to “importation” and “sale” in the violation provisions of Section 337, 19 U.S.C. §§ 1337(a)(1)(A), (B), (C), and (E), the Commission finds that the intended meaning of “articles” encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation. This meaning is consistent with the title of Section 337, “Unfair Practices in Import Trade,” which further indicates that “articles” are involved in “import trade.” *See Federal Trade Commission v. Mandel Bros. Inc.*, 359 U.S. 385, 388-89 (1959) (title of a statute is “a useful aid in resolving an ambiguity”).

Moreover, in defining a Section 337 violation in connection with statutory intellectual property rights (as in the present investigation), the term “articles” appears in the phrase “articles that infringe” a patent, a registered trademark, and a registered copyright. 19 U.S.C. §§ 1337(a)(1)(B) and (C). Similarly, with respect to protected vessel hull designs, a violation is defined by an “article,” the importation or sale of which “constitutes infringement of the exclusive rights in a design protected under chapter 13 of Title 17.” 19 U.S.C. § 1337(a)(1)(E). The Supreme Court has found that digital

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distribution of copyrighted songs and movies can infringe a U.S. copyright. *See, e.g.*, *MGM Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005). Similarly, the use of trademarks on websites, or in internet domain names, can infringe a U.S. trademark under the Lanham Act or the Anticybersquatting Consumer Protection Act. *E.g.*, *Voice of the Arab World, Inc. v. MDTV Medical News Now, Inc.*, 645 F.3d 26, 36 (1st Cir. 2011); *Coca-Cola Co. v. Purdy*, 382 F.3d 774, 778 (8th Cir. 2004). Thus, based on the statutory phrase “articles that infringe” with respect to statutory intellectual property rights in 19 U.S.C. §§ 1337(a)(1)(B), (C), and (E), the Commission finds that the meaning of “articles” is intended to encompass imported items of commerce as to which a finding of infringement of a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met).

Similarly, in defining a violation under Section 337(a)(1)(A) in connection with other “unfair methods of competition and unfair acts,” the phrase “importation of articles” appears with the description that the “articles” at issue in the subparagraph are “other than articles provided for in subparagraphs (B), (C), (D), and (E).” 19 U.S.C. § 1337(a)(1)(A). *See TianRui Group Co. Ltd. v. ITC*, 661 F.3d 1322, 1331 (Fed. Cir. 2011) (citing S.Rep. No. 67–595, pt. 1, at 3 (1922) (“The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had.”)). As an example, the Commission has held that trade secret misappropriation in the context of the importation of articles can constitute an unfair act under Section 337(a)(1)(A). *See, e.g.*, *Rubber Resins and Processes for Manufacturing Same*, Inv. No. 337-TA-849, Comm’n Op. (Jan. 15, 2014). Based on the use of the broad

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phrase “unfair methods of competition and unfair acts” in connection with “articles” in defining a violation of Section 337(a)(1)(A), the Commission finds that this subparagraph of the statute further suggests a broad meaning of “articles” that embraces imported items without limitations as to form or type of the articles.

Additional guidance as to the intended meaning of “articles” may be gleaned from the understanding of legislators considering the bill at the time of enactment. *See, e.g., Mastro Plastics Corp. v. National Labor Relations Bd.* 350 U.S. 270, 287-88 (1956) (discussing legislative reports and debates). The House and Senate Reports of the 1922 and 1930 Acts and Congressional debate refer to articles as synonymous with goods, commodities, and merchandise. *See S. Rep. 67-595 at 3 (1922); H. R. Rep. 71-7 at 3 (1929); 71 Cong. Rec. S. 3872, 4640 (1929).* The meanings of these terms, according to BLACK’S LAW DICTIONARY (2nd ed. 1910) in use at that time, indicate that the term “articles” broadly covers items that are bought and sold in commerce. *Id.* (“1. an item acquired through contract or purchase.”). These definitions do not provide any particular limitations as to specific categories of articles, or specific forms or types of articles that would fall outside the ambit of Section 337’s proscriptions. Indeed, these definitions of goods, merchandise, and commodities would encompass within their meaning various types and forms of products that are bought and sold in commerce.²² These commercial terms have retained their expansive meanings even as the fundamental nature of international commerce has evolved over the many decades since Section 337 was

²² Even if, as respondents contend, legislators in 1930 had contemplated goods, merchandise, and commodities to be the types of products traded at that time, the Supreme Court “frequently has observed that ‘a statute is not to be confined to the ‘particular application[s] . . . contemplated by the legislators.’” *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980) (quoting *United States v. Barr*, 324 U.S. 83, 90 (1945). *Accord Browder v. United States*, 312 U.S. 335, 339 (1941); *Puerto Rico v. Shell Co.*, 302 U.S. 253, 257 (1937)).

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originally enacted. We note recent developments that show the acceptance of digital goods traded in commerce as falling within international trade. Senators Baucus and Hatch and Congressman Camp have introduced Trade Promotion Authority bills that instruct the Administration to seek increased protections for digital trade in future trade agreements. S.1900, 113th Congress, introduced January 9, 2014; H.R.3830, 113th Congress, introduced January 9, 2014. Moreover, Congress has requested that the Commission study the impact of digital trade under Section 332, another part of Title 19.²³ See Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415 (July 2013) (recognizing trade in digital products as U.S. and global commercial activity).²⁴ Commenters have cited a number of industry and academic papers that have treated digital goods as articles of commerce.²⁵ Accordingly, the commercial terms that were used in the legislative history synonymously with “articles” suggest that Congress intended the statute expansively to embrace “articles” that may be traded in commerce, regardless of form or type.

²³ Following receipt of a request dated December 13, 2012 from the Senate Committee on Finance under section 332(g) of the Tariff Act of 1930 (19 U.S.C. §1332(g)), the U.S. International Trade Commission instituted investigation Nos. 332-531 and 332-540, Digital Trade in the U.S. and Global Economies, Parts I and II.

²⁴ In its Digital Trade Report, the Commission requested public comments on how to describe digital trade in the context of the broader economy. The Commission adopted the following definition of digital trade: “Defined in this report as the delivery of products and services over either fixed line or wireless digital networks. This definition includes U.S. domestic commercial activity as well as international trade. It excludes commerce in most physical goods, such as goods ordered online and physical goods that have a digital counterpart such as books and software, music, and movies sold on CDs or DVDs.” Digital Trade In the U.S. and Global Economies, Part I, Inv. No. 332-531, USITC Pub. 4415, at xii (July 2013).

²⁵ See, e.g., MPAA Reply Sub. at 10 (citing recent publications including: Joshua Meltzer, “Supporting the Internet as a Platform for International Trade,” Brookings Institution, Global Economy & Development Working Paper 69 (Feb 2014); Powering the Digital Economy: A Trade Agenda to Drive Growth,” Business Software Alliance (2014); Edward Gesser, The Internet and the Next Generation’s Global Economy,” Progressive Economy (Jan. 30, 2014); Drs. William Kerr and Chad Moutray, “Economic Impact of Global Software Theft on U.S. Manufacturing Competitiveness and Innovation,” National Association of Manufacturers and National Alliance for Jobs and Innovation (2014)).

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Importantly, the Commission must construe the term “articles” in such a manner as to faithfully implement the express purpose for which Congress enacted the statute. The central purpose of Section 337, since the enactment of the original statute in 1922, has been to prevent every type of unfair act or practice in import trade that harms U.S. industries. *See, e.g.*, S. Rep. 67-595, at 3 (1922) (“The provision relating to unfair methods of competition is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country ever had.”); *see also* H. R. Rep. 100-40 at 155 (1987).

The Commission’s reviewing courts have instructed that the terms of the statute must be construed to effectuate this central purpose of Section 337. The Court of Customs and Patent Appeals explained that Congress intended for a broad interpretation of the statutory terms of Section 337:

The statute here under consideration provides broadly for action by the Tariff Commission in cases involving ‘unfair methods of competition and unfair acts in the importation of articles’, but does not define those terms nor set up a definite standard. As was noted in our decision in *In re Northern Pigment Co.*, 71 F.2d 447, 22 C.C.P.A., Customs, 166, T.D. 47124, the quoted language is broad and inclusive and should not be held to be limited to acts coming within the technical definition of unfair methods of competition as applied in some decisions. The importation of articles may involve questions which differ materially from any arising in purely domestic competition, and it is evident from the language used that Congress intended to allow wide discretion in determining what practices are to be regarded as unfair.

In re von Clemm, 229 F.2d 441 (CCPA 1955). Similar guidance was provided by the Federal Circuit in *TianRui* in which the Court stated that “Congress intended a similarly broad and flexible meaning when it used the same language [as the Federal Trade Commission Act] to prohibit ‘unfair methods of competition’ in importation.” *TianRui*

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Group Co. Ltd. v. ITC, 661 F.3d 1322, 1331 (Fed. Cir. 2011). Pertinent to the issue of “articles,” the *Tian Rui* Court noted that “Congress contemplated that, in exercising its new authority over unfair competition, the Commission would consider conduct abroad in determining whether *imports that were the products of, or otherwise related to, that conduct* were unfairly competing in the domestic market.” *Id.* at 1332. In accordance with our reviewing Court’s instructions and to ensure that we properly implement Congressional intent, the Commission reviews the pertinent legislative history of Section 337 below.

The legislative history emphasizes the central purpose of preventing every type of unfair act or practice in connection with imported articles (assuming, starting with the Trade Act of 1974, consistency with the public interest), and endeavors to strengthen the reach of Section 337 to provide effective relief to U.S. industries that are harmed by imported articles. As the Court of Customs and Patent Appeals noted in *Frischer & Co. v. Bakelite Corp.*, “the purpose of the law is to give to industries in the United States, not only the benefit of favorable laws and conditions to be found in this country, but also to protect such industries from being unfairly deprived of the advantage of the same and permit them to grow and develop.” 39 F.2d 247, 259 (C.C.P.A. 1930). *See also In re Orion Co.*, 71 F.2d 458 (CCPA 1934) (“these various provisions were intended to shelter, protect, and conserve the industries of the United States, as well as to provide revenues.”).

The legislative history of the 1930 Act demonstrates Congress’s continuing concern with protection of U.S. industries from unfairly traded imported articles. *See, e.g.*, H.R. Rep. 71-7 at 166 (1929); S. Rep. 71-37, at 68 (1929). This legislative history

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also evinces Congress's recognition that innovation would yield many new types and forms of articles that would be traded in commerce in the future. For example, a Congressional Report accompanying the Tariff Act of 1930 recognizes that many new goods and manufacturing processes had been invented and brought to the U.S. market since the 1922 Act, and anticipates that many new goods and processes would come in the future. H. R. Rep. 71-7 at 3-4. It was also noted that U.S. industries needed protection from competition, particularly unfair competition, so that they could come forward with these new goods and processes. *See id.* at 4, 166. This forward-looking recognition in the legislative history that innovation would bring new goods to the U.S. market, and that U.S. industries needed protection against unfairly traded goods to foster such innovation, indicates that the term "articles" should be construed flexibly to fit new technologies. *See Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980) ("Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."); *WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 627 (7th Cir. 1982) (Congress intended definitions to be interpreted flexibly so that as new technologies appeared, Congress wouldn't have to update the statute periodically).

Likewise, the Trade Act of 1974 strengthened the statute to protect against unfairly traded imports by providing additional remedies for a violation, namely cease and desist orders, and by providing authority to the Commission itself to administer the statute and issue remedies. In so doing, the legislative history echoes the concerns of previous Congresses that Section 337 should provide strong protections against unfair

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acts in connection with imported articles. *See, e.g.*, H.R. Rep. 93-571 at 77-79 (1973); S. Rep. 93-1298 at 193-200 (1974).

By the mid-1980s, Congress recognized the growing problems that infringing imports posed for U.S. intellectual property rights owners. The Omnibus Trade and Competitiveness Act of 1988 further strengthened Section 337 with respect to the protection of intellectual property rights and expressed the will of Congress to encompass within its scope infringing imports:

Any sale in the United States of a product covered by an intellectual property right is a sale that rightfully belongs to the holder or licensees of that property. The importation of ***any infringing merchandise*** derogates from the statutory right, diminishes the value of the intellectual property, and thus indirectly harms the public interest.

S. Rep. 100-71 at 128-29 (1987) (emphasis added); H.R. Rep. 100-40 at 156 (1987) (same).

In further amending Section 337 in the Uruguay Round Agreements Act of 1994, Congress continued to emphasize the focus of Section 337 as authorizing the Commission “to exclude goods from the United States and enjoin activities with respect to imports that are found to infringe U.S. intellectual property right or are otherwise found to violate that statute.” H.R. Rep. 100-826 at 140. The 1994 Act made certain procedural changes to remove the time limits on Commission proceedings and to stay simultaneously filed parallel district court litigation. H.R. Rep. 100-826 at 140 (1994); S. Rep. 103-412 at 118 (1994). The 1994 amendments made no change in the substance of the unfair acts or scope of the articles that are subject to a finding of a statutory violation.

Respondents urge the Commission to find that the term “articles” cannot be construed to include within its meaning the subject digital data sets that are electronically

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transmitted into the United States, relying principally upon the Federal Circuit's decision in *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 (Fed. Cir. 2003). Resp. Sub, at 2-4. *Bayer*, however, is of limited relevance to the proper construction of the statutory term "articles," and does not mandate a different conclusion. At issue in *Bayer* was a patented method for screening substances to ascertain whether the substance inhibits or activates a particular protein. *Id.* at 1369. The practice of the patent there resulted in "information in the abstract," specifically, "the knowledge that a substance possesses a particular quality." *Id.* at 1371-72, 1376. Housey alleged that Bayer was liable as an infringer under 35 U.S.C. § 271(g), *not* 19 U.S.C. § 1337 (a)(1)(B), when it imported this "knowledge" or "information" obtained from performing the Housey patented methods. In finding that § 271(g) did not cover this type of abstract research data or information, the Federal Circuit held that the statutory term "made" in § 271(g) means "manufactured." According to the Court, the production of the information at issue was not within the scope of "manufacture."

In its analysis, the Federal Circuit examined the 1988 legislative history of 35 U.S.C. § 271(g) and Section 337(a)(1)(B)(ii). In so doing, the Court did not purport to ascertain the parameters of the Commission's Section 337 jurisdiction, but rather was construing 35 U.S.C. § 271(g). Indeed, the Court noted in a footnote that Section 337 may have a broader scope than 35 U.S.C. § 271(g), although it observed, without analysis, that Section 337 does not indicate that § 271(g) covers the type of "information" about the inhibitive or activating characteristics of a substance obtained through the practice of the process patent that was at issue in that case. *Id.* at 1374 n.9 ("We recognize that section 1337 covers both articles that were 'made' and articles that were

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‘produced, processed, or mined.’ While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g.”). As is clear from the Court’s recitation of the specific “information” pertaining to the patent at issue in that case, that “information” obtained through the practice of the patent at issue in *Bayer* was whether a substance was an inhibitor or an activator of a protein. Thus, *Bayer* provides little, if any, guidance concerning the articles at issue here. In contrast to *Bayer*, the articles at issue here comprise infringing digital data sets that are models of an individual patient’s teeth, as well as the aligners made therefrom, that result in incremental movements of those teeth through successive orthodontic treatments.

Comments of third party submitters present practical considerations that echo the concern of legislators in enacting Section 337 in order to protect U.S. industries against unfairly traded imports. The Motion Picture Association of America (“MPAA”) and the Association of American Publishers (“AAP”) describe the transition by IP-based industries to digital distribution (including industries producing motion pictures, software, books, music and games). MPAA Sub. at 2; AAP Sub. at 2. Both groups describe the problems of infringement by illegal download and streaming, and the importance of Section 337 to IP-based industries.²⁶ They point out that protecting the copyrights of U.S. companies from the importation of these infringing articles that are electronically transmitted by foreign sources is consistent with the intent of Congress and the longstanding purpose of Section 337. MPAA Sub. at 10-13; AAP Sub. at 3.

²⁶ MPAA estimates the cost of such infringement to the U.S. economy at \$58 billion annually, including more than 373,000 jobs, \$16 billion in lost employee earnings, and \$3 billion in federal, state, and local tax revenue. MPAA Sub. at 2-3. MPAA cites numerous Congressional and industry studies that have estimated losses to the U.S. economy due to such IP infringement. *Id.* at 2-4.

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MPAA also points out that construing “articles” in Section 337 to cover electronic transmissions is consistent with established practices of U.S. Customs and Border Protection (“CBP”) and the Department of Labor (“DOL”). MPAA notes that CBP, which is charged with interpreting and administering the Harmonized Tariff Schedule of the United States (“HTSUS”), has ruled that the transmission of software modules and products into the United States via the internet constitutes an importation of foreign merchandise into the United States. MPAA Sub. at 8 (citing HQ 114459, 1998 US CUSTOM HQ LEXIS 640 (Sept. 17, 1988)). Similarly, MPAA notes that DOL, which administers trade adjustment assistance to U.S. workers displaced by imported products under the Trade Adjustment Assistance Act,²⁷ has ruled as a matter of policy that “[s]oftware and similar intangible goods that would have been considered articles . . . if embodied in a physical medium will now be considered to be articles regardless of their method of transfer. *Id.* (citing 71 Fed. Reg. 18355, 18357 (Apr. 11, 2006)).²⁸ We more broadly observe that MPAA’s submission shows that U.S. federal agencies charged with responsibilities over international trade agree that digital merchandise are articles of international commerce.

²⁷ The Trade Adjustment Assistance Act (“TAA”) was part of the Trade Expansion Act of 1962, Pub. L. 87-794, 76 Stat. 883.

²⁸ MPAA also cites a 2006 CIT decision finding that electronic transmissions of software were “articles produced” within the meaning of the TAA. MPAA Sub. at 8-9 (citing *Former Emps. of Computer Scis. Corp. v. Secretary of Labor*, 414 F. Supp.2d 1334 (Ct. Int’l Trade 2006); *Former Emps. Of Merrill Corp. v. United States*, 483 F. Supp. 2d 1256, 1257-68 (Ct. Int’l Trade 2007)). We note, for completeness, a Federal Circuit decision in *Woodrum v. United States*, 737 F.2d 1575 (Fed. Cir. 1984), “affirm[ing] on the basis of [the CIT] opinion,” 564 F.Supp. 826, 829 (CIT 1983). In the CIT opinion, the CIT construed the TAA language “articles produced” such that “production under section 222(3) requires the manufacture or creation of something tangible” and therefore affirmed the Labor Secretary’s denial of TAA benefits to mechanics employed by an independent automobile dealership who service and prepare vehicles for retail sale because they “have not transformed articles into new and different articles.” 564 F.Supp. 2d at 829. Similarly, in *Nagy v. Donovan*, 571 F. Supp. 1261, 1264 (Ct. Int’l Trade 1983), the CIT held that employees who provide automotive services do not engage in production of a new and different article.

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Third party Google notes that Commission exclusion orders (and seizure and forfeiture orders) enforced by U.S. Customs and Border Protection relate only to physical goods passing through U.S. ports of entry, and thus would not remediate violations involving electronically transmitted articles. *See* Google Sub. at 6-7. Exclusion orders, however, are not the exclusive remedy for violations of Section 337.²⁹ The statute provides for highly effective remedies in the form of cease and desist orders under Section 337(f), to prevent further electronic shipments of infringing goods. 19 U.S.C. § 1337(f)(1). Under Section 337(f), cease and desist orders may be issued “[i]n addition to, or in lieu of” an exclusion order. The Commission vigorously enforces violations of cease and desist orders, and under the statute, may impose civil penalties for violations of up to \$100,000 per day. 19 U.S.C. § 1337(f)(2). Moreover, the Commission’s cease and desist orders typically require the posting of a bond with the Office of the Secretary to cover continued prohibited conduct during the Presidential review period “in an amount determined by the Commission to be sufficient to protect the complainant from any injury.” 19 U.S.C. § 1337(j)(3). Thus, the fact that Customs enforces exclusion orders issued by the Commission by excluding from entry physical goods passing through U.S. ports does not limit our understanding of the scope of “articles.” It should be noted that

²⁹ It is a feature, not a flaw, for a set of remedy provisions to include some subsections that apply only in some settings; and agencies are given deference on their choices about which statutory remedy to apply so they can appropriately address the particular facts of each case. *See Butz v. Glover Livestock Commission Company, Inc.*, 411 US 182, 188 (1973) (agencies must carefully weigh their selection of authorized remedy based on the evidence and the statutory scheme); *Mourning v. Family Publications Service, Inc.*, 411 US 356, 371-72 (“We have consistently held that where reasonable minds may differ as to which of several remedial measures should be chosen, courts should defer to the informed experience and judgment of the agency to whom Congress delegated appropriate authority.”) This helps to ensure that at least some remedy is available for a violation. *See S. Rep. 93-1298* at 198 (1974) (explaining the provision for cease and desist orders in the new amendment to Section 337) (“It is clear to your committee that the existing statute, which provides no remedy other than exclusion from entry, is so extreme or inappropriate in some cases that it is likely to result in the Commission not finding a violation of this section, thus reducing the effectiveness of section 337 for the purposes intended.”).

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in this investigation, complainant Align requests only cease and desist orders, as discussed more fully in Part IV below.

Third parties Nokia, the AAP, and the MPAA caution that "articles" should not be construed in such a way that infringers could avoid liability under Section 337, thereby denying an avenue of relief to IP-based industries in the United States. AAP Sub. at 2; MPAA Sub. at 6; Nokia Reply Sub. at 9. For example, an infringer could shift from importing its infringing software on a disk to importing the very same software by electronic transmission. They note that "it would be anomalous for the Commission to be able to stop the transfer of a CD-ROM or diskette containing the respondents' software but not be able to stop the transfer of the very same software when transmitted in machine readable form by electronic means." MPAA Sub. at 6; AAP Sub. at 2. The Commission concurs. "It has been called a golden rule of statutory interpretation that, when one of several possible interpretations produces an unreasonable result, that is a reason for rejecting that interpretation in favor of another which would produce a reasonable result." 2A Singer, Sutherland Statutory Construction § 45.12 (7th ed. 2007). The Commission concludes, in the context of this case, that an interpretation of "articles" that allows the Commission to reach the imported physical aligners at issue in Investigation No. 337-TA-562, but does not include the infringing digital data sets from which the aligners are produced, simply because they are in digital form, is unreasonable and inconsistent with the purpose of the statute.

Finally, a few commentators argue that principles of patent law preclude a finding that electronic data transmissions constitute "articles" under Section 337. Google Sub. at 10-13; Katz Sub. at 3, 8 (citing *In re Nuitjen*, 500 F.3d 1346, 1353 (Fed. Cir. 2007)).

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They argue that because an electronic transmission is not patent eligible subject matter under 35 U.S.C. § 101, section 337 should not be construed to include electronic transmissions. The Commission disagrees with this view. First, the question we are deciding – whether the “importation . . . of articles” includes digital data sets that are electronically transmitted into the United States – goes to the importation requirement, not patent eligibility *per se*.³⁰ Second, the argument overlooks the fact that in defining a Section 337 violation in connection with statutory intellectual property rights the term “articles” appears in the phrase “articles that infringe” a patent, a registered trademark, and a registered copyright. Thus, the commenters fail to take into account that the phrase “articles that infringe” is not simply limited to patents, but also applies to trademarks and copyrights, as well as other unfair acts and methods of competition in connection with importation and sale of articles.³¹ Third, section 337 is a trade statute that is part of Title 19. As we observe above, there is a consensus among government agencies charged with responsibilities over international trade that digital merchandise are articles of

³⁰ In this investigation, respondents did not raise any § 101 arguments concerning the asserted patents. Furthermore, any such arguments are more properly addressed regarding validity, not importation, and the Commission may not invalidate a patent claim *sua sponte*, i.e., where invalidity has not been asserted by the respondent as a defense to infringement of a properly asserted claim. See generally, *Lannom Mfg. Co. v. United States Int'l Trade Comm'n*, 799 F.2d 1572, (Fed.Cir.1986). We also note that the commenters may not be correct in their suggestion that the patent claims at issue would be invalid under § 101. In cases such as this one, where the digital data sets cause a physical arrangement (here, where to place the mechanical braces used to align human teeth), the Federal Circuit has determined that §101 would be satisfied, *see In re Alappat*, 33 F.3d 1540 (Fed. Cir. 1994) (*en banc*) (digital data produced a “useful, concrete, and tangible result” in the form of a smooth curve displayed on the screen). Similarly, in cases such as this one where the digital data sets correspond to a “useful, concrete, and tangible” thing (here, the relative locations of the human teeth), the Federal Circuit has determined that § 101 is satisfied, *see also Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed.Cir.1992) (digital data set corresponded to electrical signals in a human heart).

³¹ We note, in the sections that follow, that we find that the subject imports are processed by means of patented processes and are materials for use in practicing patented processes. Here, we are solely construing the statutory term “importation . . . of articles” in the violation provisions of Section 337.

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international commerce. Accordingly, we reject these arguments presented by Google and Katz.

In sum, our task is to determine whether the phrase “importation … of articles” encompasses this modern form of international commerce, or should be understood as limited to the kinds of international transactions in existence when the statute was first enacted. Having carefully reviewed the plain language of the statute, its legislative history and purpose, pertinent case law, and the arguments of the parties and public commenters, we conclude that the statutory phrase “importation … of articles” should be construed to include electronic transmission of digital data because the digital data sets at issue in this investigation are true articles of international commerce that are imported into the United States and their inclusion within the purview of section 337 would effectuate the central purpose of the statute.

B. Claim Construction**1. One of Ordinary Skill in the Art**

The ALJ found that one of ordinary skill in the art at the time of the invention of the asserted claims of each of the patents at issue in this investigation was an individual with expertise in digital modeling and analysis and a working knowledge of orthodontic principles. ID at 28.

Align argues that it showed that one of ordinary skill in the art at the time of the inventions for each of the asserted patents would include a practicing orthodontist. Align Pet. at 33.

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The issue does not affect the outcome of the investigation. However, the issue is undisputed and the Commission agrees with Align that practicing orthodontists are also persons of ordinary skill in the art.

2. “a predetermined series of dental incremental position adjustment appliances”/“predetermined series of dental incremental position adjustment appliances” (the ‘880 patent)

The term “a predetermined series of dental incremental position adjustment appliances”/“predetermined series of dental incremental position adjustment appliances” appears in asserted claim 1.

The parties dispute the meaning of “predetermined series” and whether or not the phrase “predetermined series” includes all appliances to be used in treatment (not just a subset) and whether or not all of those appliances must be fabricated before any treatment begins. ID at 52. The ALJ found that the claims and the specification do not support Respondents’ argument that the “repositioned tooth arrangement” would have to be further limited to mean the final tooth arrangement at the *end of treatment*. ID at 54. The ALJ explained that the specification teaches that target intermediate tooth arrangements (“key frames”) are defined and intermediate digital data sets are generated between the target intermediate tooth arrangements, rather than just between the initial and final tooth arrangements. *Id.* (citing JX-0002 at 6:56-67).

The ALJ found that claim 1 requires a method that comprises four steps that are performed in order. *Id.* at 52. The ALJ reasoned that, although method claims are not ordinarily construed to require a particular order of steps, here the claims require they be performed in the order written. *Id.* (discussing *Interactive Gift Exp., Inc. v. Compuserve*

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Inc., 256 F.3d 1323, 1342 (Fed. Cir. 2001)). The ALJ explained that each subsequent step in claim 1 necessarily requires the previous step to have been executed.

Align argues that the ALJ should not have construed claim 1 of the ‘880 patent to require that the steps be performed in an ordered process. Align Pet. at 25. Align argues that one need not obtain a “repositioned tooth arrangement” before obtaining the “series of successive digital data sets.” *Id.* Align argues that the Respondents waived any such construction, and that the ALJ further erred in finding that the fourth claim element builds on the third claim element. *Id.* (citing JX-0002 at 22:26–28).

The Respondents did not comment on this claim construction in their petition or response, or in their briefing on review.

We agree with the ALJ that each step of claim 1 of the ‘880 patent assumes the prior completion of the previous step.³² For example, step b is “based on the initial tooth arrangement” of step a. The digital data sets of step c are based on the tooth arrangements of step b. The dental appliances of step d are based on the digital data sets of step c. We therefore affirm the ALJ’s claim construction of these terms, and adopt the ALJ’s reasoning, as set forth in the ID at 51-58, including his construction that the predetermined series can be constructed prior to an intermediate aligner and need not be prior to the fabrication of all aligners. See ID at 54-55 (discussing how repositioned tooth arrangements include intermediate tooth arrangements and not just final tooth arrangements).

³² The ALJ was not precluded from deciding that the correct claim construction is one that was not argued. See *Exxon Chemical Patents Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1558 (Fed. Cir. 1995) (Court did not adopt the construction proposed by either party).

PUBLIC VERSION**3. “treatment plan” (the ‘487 patent and the ‘874 patent)**

The term “treatment plan” appears in asserted claims 7, 8 and 9 of the ‘487 patent and claim 1 of the ‘874 patent.

The ALJ found that Respondents waived the right to offer a construction for the term “treatment plan.” ID at 68 (citing Second Revised Joint Claim Construction Chart (“SRJCCC”) at 8 (“No construction proposed.”)). The ALJ found that the plain language of claim 7 of the ‘487 patent defines a “treatment plan” as “two or more successive digital data sets representing arrangements of a patient’s teeth progressing from an initial tooth arrangement toward a final tooth arrangement.” ID at 68-69. The ALJ found that claim 7 is not limited to final arrangements that are prescribed. *Id.* at 70. The ALJ relied on the plain language of claim 7, which provides that the “treatment plan” comprises “a plurality of intermediate digital data sets.” *Id.* at 68-69 (citing ‘487 patent, col. 11, lines 26-35.) The ALJ explained that claim 7 continues to explain that the intermediate digital data sets “represent[] intermediate arrangements of the patient’s teeth,” and the final data set “represent[s] the patient’s teeth in a desired or prescribed arrangement.” *Id.* at 69 (citing ‘487 patent, col. 11, lines 26-35). The ALJ continued that the specification supports this understanding of beginning, middle, and final tooth arrangements. *Id.* at 69-70 (citing ‘487 patent, col. 8, lines 38-47).

The Respondents argue that the plain and ordinary meaning of “treatment plan” is the course of treatment devised by the treating dentist or orthodontist, not by a dental lab like CCUS. Resp. Pet. at 63. The Respondents highlight that Align’s expert, Dr. Valley, relied on the provisional application for priority, which states: “[u]sing treatment planner software, the orthodontist then creates a series of intermediate treatment states.” *Id.*

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(referring to CX-1247C at Q. 115; CX-1252-007). The Respondents further point to the testimony of Mr. Jarrett Pumphrey, a witness for CCUS, and Dr. Willis Pumphrey, an orthodontist, who stated that dental labs like ClearCorrect do not prepare treatment plans. *Id.* (citing Tr. 415:4-11; Tr. 350:15-351:13). Respondents also note that Dr. Pumphrey stated that treatment by the physician is a matter of law and industry standard. Tr. 415:12-14.

Align argues that the ALJ misconstrued the claim term “treatment plan” in claim 1 of the ‘874 patent and claim 7 of the ‘487 patent. Align Pet. at 23. Specifically, Align states that the ALJ improperly imposed a requirement that the “treatment plan” include “successive digital data sets.” Align argues that there is no requirement that an “initial tooth arrangement” be present in the “treatment plan,” but that the ALJ’s construction is ambiguous in that regard. *Id.* Align also argues that Respondents’ proposed construction is based on a single embodiment described in a provisional application to which the ‘487 Patent claims priority, and that this limitation cannot be imported into the claim. Align Resp. to Resps. at 47 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996)). Align further argues that Respondents ignore the *other* embodiments described in the specification - - that either an “orthodontist or other operator” may perform the steps of treatment planning. *Id.* (quoting CX-1252 at 13).

The Commission has determined to affirm the ALJ’s construction of “treatment plan,” and adopt the ALJ’s reasoning, as set forth in the ID at 68-74 and 102-104. By the terms of claim 7, it is the “final arrangement representing the patient’s teeth” which is “desired or prescribed.” ‘487 patent, col. 11, line 34; see also col. 1, lines 37-41

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(Background of the Invention); col. 11, lines 26-35. There is no requirement that the “intermediate digital data sets” are themselves prescribed by the dentist. Rather, the purpose of the invention is to allow a computer to calculate these intermediate positions based on the patient’s initial and the prescribed final position. *See Figure 3 (flow chart)*; col. 5, lines 56-61.

4. “computer-implemented method” (the ‘511 patent and the ‘874 patent)

The term “computer-implemented method” appears in the preamble to asserted claim 1 of the ‘511 patent and claim 1 of the ‘874 patent.

The ALJ found that “computer-implemented method” means “a method accomplished using a computer.” The ALJ found the preamble to be limiting.

Align argues that the ALJ erred in finding that the claim term “computer-implemented” should be read into each element of claim 1 of the ‘511 patent and claim 1 of the ‘874 patent, *i.e.*, Align argues that the preamble does not place a restriction on each claim element to be computer-implemented. Align Pet. at 26. Align argues that Respondents waived such an argument, and that even where a court finds a preamble limiting, the limitation is not necessarily read into each element of the claim. *Id.* at 26 (citing *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323 (Fed. Cir. 2005), vacated on other grounds sub. nom. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006)). Align points, *inter alia*, to the specification of the ‘511 patent, which teaches that generating the appliances may be done manually. *Id.* at 26-27 (citing ‘511 patent at 5:1-6).

The Respondents did not comment on this claim construction in their petition, response, or briefing on review.

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The Commission has determined to affirm the ALJ's construction of "computer-implemented method" in claim 1 of the '511 patent and claim 1 of the '874 patent, and adopt the ALJ's reasoning, as set forth in the ID at 77-81 and 93-97. The ALJ is correct that the preamble is limiting in this case because it provides structure, *i.e.*, it explains that the computer will be performing the calculations. *See, e.g., Catalina Mktg. Int'l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002) (one of the types of preamble that is limiting is a preamble that provides necessary structure). While we agree with the ALJ that the claims do not preclude human supervision or intervention as a supplement to computer computation, the both patents teach that the interpolations are performed by a computer. *See, e.g.*, '874 patent (Abstract) (A computer is used to create a plan . . ."); '511 patent, col. 1, line 23-24 (Background of the Invention) ("The present invention relates to computational orthodontics"). Further, a computer may be used to provide the original digital data set for interpolation, *see* '511 patent, col. 5, line 44 – col. 6, line 5, and to manufacture ("generate") the appliance from the digital data sets through an automated process. *See* '511 patent, col. 5, lines 1-5; '874 patent, col. 30, lines 9-13. The patent's specification and claims plainly contemplate the use of a computer for each step. *See also* '511 patent, col. 3, line 64 - col. 4, line 4 (discussing digital models of initial and final data sets); '874 patent, col. 11, lines 49-61. Similarly, the aligners are fabricated using models of the teeth based on the computer program. *See, e.g.*, '511 patent, col. 5, line 1-5 (discussing using automated processes and electronic information for manufacturing); '874 patent, col. 19, line 30-59 (discussing using data sets and application software for manufacturing).

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5. “distinct successive incremental dental positioning appliance”/“successive incremental dental positioning appliance” (the ‘863 patent)

The term “distinct successive incremental dental positioning appliance” appears in asserted claim 1.

The ALJ found that “distinct successive incremental dental positioning appliance”/“successive incremental dental positioning appliance” means “a single, separate appliance to be used during a particular interval for repositioning teeth.”

The ALJ found that the claim language only requires that two or more digital models be produced. ID at 87-88 (citing *Apple Inc. v. Samsung Electronics Co., Ltd.*, 695 F.3d 1370, 1379 (Fed. Cir. 2012); *August Technology Corp. v. Camtek, Ltd.*, 655 F.3d 1278 (Fed. Cir. 2011)). The ALJ found that use of the term “successive” in conjunction with the terms “distinct” and “incremental” does not require fabrication of “a series.” The ALJ further found that the specification and prosecution history of the ‘863 patent describe replacing attachment devices mid-treatment or placing new attachment devices throughout treatment, JX-005 at 7:61-64; CX-1251 at 212, and teaches away from fabricating all of the dental appliances prior to the outset of treatment. ID at 88-89.³³

There are two issues on review: whether there is more than one dental appliance and whether dental appliances are all fabricated before the beginning of treatment. Align argues that the ALJ misconstrued the claim term “distinct successive incremental dental positioning appliance” in claim 1 of the ‘863 patent. Align further argues that the ALJ was correct to reject late-proposed limiting constructions by the Respondents but

³³ ID at 89 (citing ‘863 patent, col. 7, lines 61-64; CX-1251 at 212). The ALJ found that Respondents had waived any proposed claim construction of this term because they relied on plain meaning in the SRJCCC. The ALJ further granted Align’s first motion in limine and excluded that portion of Question 120 of Dr. Mah’s testimony upon which Respondents rely to support their waived argument on construction.

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disagrees with the ALJ's construction to the extent it disassociates the appliance from the series of which it is a part.

The Respondents do not discuss Align's contingent petition for review in their response or briefing on review. *Resps. Resp. at 9.*

The IA argues that the ALJ correctly construed the disputed claim terms and suggests that Align's disagreement with the ALJ's claim constructions has no bearing on the current dispute.

Although the claim construction has no bearing on the resolution of the current dispute, the Commission reverses the ALJ's construction and concludes that claim 1 requires a series of dental appliances. Although the specification mentions "one or more attachment devices," the '863 patent, col. 3, lines 14-15, the claims recite a "plurality" of modified digital models in the claims, each to be used to fabricate "successive" appliances. '863 patent, Ex Parte Reexam. Certificate, col. 1, line 60, 64-65. We note, however, that nothing requires the entire series to be manufactured before treatment begins. *See* '863 patent, col. 7, lines 61-64.

6. "providing" (the '325 patent)

The term "providing" appears in all of the asserted claims of the '325 patent. This claim construction issue arises from the ALJ's infringement analysis. The Respondents argue that the ALJ's infringement analysis indicates an inconsistent use of the term "providing" by the ALJ. The Respondents argue that while, for most asserted claims in this investigation, the ALJ found that CCPK provided information to CCUS or that CCUS provided information to CCPK, with respect to claim 31 of the '325 patent the ALJ found that CCPK "provides" the initial digital data set internally to itself. *Resps.*

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Pet. at 61-62 (citing ID at 475, 512).³⁴ The Respondents argue that the ALJ apparently realized that his application of the term “providing” is tortured because he stated in the ID that “Mr. Beers [the witness] clearly did not intend to say that CCUS provided digital models to itself, and such a statement was clearly in error,” ID at 435, in explaining that the witness meant to say CCPK instead of CCUS. *Id.*

Align argues that the ALJ applied a consistent interpretation of the term “providing” across the claims. Align Resp. to Resps. at 44. Align argues that in the context of the asserted claims and intrinsic evidence, the ALJ interpreted the term “providing” to broadly cover both transmitting to an external entity or uploading into a computer or machine. *Id.* (discussing ID at 475). Align argues that the ALJ found CCPK provides the digital data set to the FreeForm software, not to itself. *Id.* (discussing ID at 475, 512). Align further argues that Respondents’ argument regarding the meaning of “providing” is waived because they failed to identify the term “providing,” and their newly-advanced limiting construction in any of the *Joint Claim Construction Charts* (“JCCC”). *Id.*

The IA argues that the Respondents’ arguments with respect to the claim term “providing” should be rejected because, as admitted by ClearCorrect, the parties did not ask that the term be construed beyond its plain and ordinary meaning. IA Resp. at 22. The IA further argues that the Respondents cite no support for their proposed limitation and the claim language does not recite any restriction as to whom or to what the “providing” is directed. *Id.*

³⁴ The Respondents argue that the ALJ made the same inconsistent use when he held that CCUS “provides” the modified digital data sets it actually receives from CCPK. *Id.* (citing ID at 502). The Commission does not view this usage of providing as inconsistent.

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While Respondents challenge the ALJ's use of "providing" in his infringement analysis, the issue is really one of claim construction. Even where the term "providing" is used only once in a patent claim (as in claim 1 of the '325 patent), the ALJ found that both CCUS and CCPK both provide data. ID at 475. The required "providing" of data may occur by the transmission of data from CCUS to CCPK, from CCUS to CCPK, from CCUS to a computer, or from CCPK to a computer. In claim 1, with respect to one occurrence of the term "providing," the ALJ found that both CCUS and CCPK satisfied the same claim term. The ALJ found that CCUS provides the initial data set to CCPK and also that CCPK provides the initial data set to a computer (by uploading the data). ID at 436, 475. Regarding the first element of claim 11, the ALJ found that CCUS provides an initial data set to CCPK and CCPK provides an initial data set to a computer; regarding the second element of claim 11, the ALJ found that CCPK provides the final data set to CCUS and CCUS provides the data set to a treatment professional. ID at 490. Regarding claim 21, the ALJ found that CCUS provides a digital data set to a computer and also that CCPK provides a data set to CCUS. ID at 502-03. The ALJ found the first through sixth elements of claim 31 to be identical to claim 1, and found that CCPK transmits the intermediate data sets to CCUS (and found an admission that CCUS imports them into a computer). ID at 512-13. The ALJ found that CCUS and CCPK both practice the first and second elements of claim 35 and claim 38. See ID at 522, 527-28.

In our view, the ALJ used the term "providing" in accordance with its plain and ordinary meaning of conveying or giving, including by "electronically transmitting." This is consistent with the meaning of "providing" within the specification. *See, e.g.,* '325 patent, col. 5, lines 36-41 ("Conveniently, the initial digital data set may be *provided*

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by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like.”)(emphasis added). It does not matter if the electronic transmission was to a computer owned by another individual or to a computer owned by the same individual. The patent claims do not make a distinction as to who receives the transmission. The plain language of the claims simply requires “providing.” The Commission therefore affirms the ALJ’s construction of “providing” with this clarification.

7. The Standard for Claim Construction As to Claims 1 and 33 of the ‘325 patent, Claim 2 of the ‘511 patent, and Claim 2 of the ‘874 patent

The ALJ provided the “broadest, reasonable” construction with respect to claims 1 and 33 of the ‘325 patent, claim 2 of the ‘511 patent, and claim 1 of the ‘874 patent. The ALJ relied on *Genentech, Inc. v. Chiron Corporation*, 112 F.3d 495, 499 (Fed. Cir. 1997), for the “broadest reasonable construction” standard. *See* ID at 81 n.9; 97 n.12 and 9. This is, however, the standard for an interference (or reexamination) at the PTO, *see Genentech*, 112 F.3d at 496-96, and is not the appropriate standard for claim construction in the context of an infringement analysis in district court or at the Commission, *i.e.*, claim terms are interpreted as they would be understood by a person of ordinary skill in the art in light of their ordinary meaning, the intrinsic evidence of the specification and the prosecution history, and certain extrinsic evidence. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (*en banc*). Nevertheless, the Commission agrees with the ALJ’s ultimate claim construction of these four claims. As set forth below, the ALJ correctly interpreted the claims in light of the specification and other

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intrinsic evidence. Thus, we have concluded that the ALJ's incorrect statement of the standard is harmless error, as his claim construction is consistent with an application of the correct standard for claim construction.

With respect to claims 1 and 33 of the '325 patent, the ALJ's claim construction of "at the outset of treatment" was correct because the ALJ properly rejected a prosecution history disclaimer argument which was based on claim language that is not present in claims 1 and 33 of the '325 patent. ID at 39.

With respect to claim 2 of the '511 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification contemplates direct interaction with the computer by a clinician who may reset the final position(s) of teeth and specify constraints to be applied to segmented paths. ID at 80 (citing JX-001, 4:36-50).

With respect to claim 1 of the '874 patent, the ALJ correctly construed "a method accomplished using a computer," finding that the specification allows user modification: "some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation"; "[d]eveloping an orthodontic treatment plan for a patient involves manipulating the IDDS [Initial Digital Data Set] at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images"; and Figure 3 of the '874 patent illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS [final digital data set] on the computer. ID at 95-96 (citing JX-006, 3:51-53, 10:12-15, 12:4-6, 12:11-44, 12:53-62).

PUBLIC VERSION**8. Waiver of Other Arguments**

With the exception of the claim terms “providing” and “treatment plan,” the Respondents do not make specific arguments in their petition for review regarding claim construction or infringement, but rather attempt to stand on and incorporate by reference their contentions about claim construction and infringement from their post-hearing brief and post-hearing reply brief before the ALJ, and as summarized by the ALJ in his ID. Resp. Pet. at 64-65. We find these arguments to be waived under Commission rule and practice. *See* 19 C.F.R. § 210.43(b)³⁵; *see also Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362 (Fed. Cir. 1999) (“A party seeking review in this court of a determination by the Commission must ‘specifically assert’ the error made by the ALJ in its petition for review to the Commission.”).

The Respondents argue that incorporation by reference is reasonable because the ALJ’s ID is 814 pages long and his analysis of claim construction and infringement spans approximately 421 pages. Nevertheless, the Respondents did not make any motion for an extension of the 100 page limit to the petition for review. Instead, the Respondents submitted a petition for review of 72 pages, with the argument for incorporation by reference. Moreover, to the extent that most of the claim terms and elements of the claimed processes are common to multiple claims and multiple patents, the Respondents could have made arguments directed to most of the elements of the claimed processes without the repetition found in the ALJ’s ID.

³⁵ The Commission stated in its recent rulemaking that it “believe[d] . . . incorporation by reference to be inconsistent with the existing rule [*i.e.*, the former version of the rule].” 76 Fed. Reg. 23474, 23479 (April 19, 2013). Thus, the Commission considered the recent rule to be a clarification, and a prohibition on any attempt at an end-run around the existing rule, rather than a new rule.

PUBLIC VERSION**C. Infringement**

As set forth herein, the Commission has adopted the ALJ's finding that the CCUS and CCPK accused products satisfy the claim limitations as construed. The Commission herein analyzes whether infringement has been demonstrated in light of the requirements of Section 337 for each of the four asserted groups of claims. There is also an issue with respect to the Group I claims as to whether the elements of 35 U.S.C. § 271(c) are satisfied.

1. Group I Claims (Claims 21 and 30 of the '325 patent; Claim 1 of the '880 patent)³⁶

a. Direct Infringement

The Group I claims are directed to methods of manufacturing dental appliances starting with a digital data set. Prior to the accused manufacturing activity related to these claims, CCPK manipulates the digital models, thereby generating intermediate and final digital data sets in Pakistan, and electronically transmits them to CCUS in the United States. ID at 472-73. Then, as relevant to these claims, CCUS uses the generated data sets to prepare molds of the patient's teeth which are in turn used to make the physical dental appliances in the United States. ID at 473 (citing Tr. at 172:15-173:8; 316:12-318:11; CX-1150C at 200-11).

As to the '325 patent, the ALJ found that CCUS independently practices each and every limitation of asserted claim 21 in the United States, and that CCPK and CCUS act

³⁶ Align includes these claims in both Group I and Group IV. Align includes the claims in Group I because the ALJ found that CCUS practices the claims entirely in the United States when it "provides" the data to the fabrication machine. The ALJ also found that CCPK acts in concert with CCUS, which would place the claims in Group IV, because CCPK "provides" the data to CCUS. As noted in our claim construction section, we understand "provide" to include conveying by an electronic transfer. Therefore, these claims can be analyzed with CCUS as the sole infringer when it electronically transfers the data to the computer and also with CCPK as a joint infringer when it electronically transfers the data set to CCUS.

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in concert to practice claim 21 of the ‘325 patent when the digital data sets created by CCPK are used by CCUS to fabricate aligners (“dental appliances”). ID at 502-503. Similarly, the ALJ found that CCUS independently, and CCUS and CCPK acting in concert, practice dependent claim 30 of the ‘325 patent. ID at 505.

As to the ‘880 patent, the ALJ found that CCUS independently practices each and every limitation of claim 1 and that the concerted efforts of CCUS and CCPK practice each and every limitation of claim 1 when the digital data sets created by CCPK are used by CCUS to fabricate aligners. ID at 571-72.

The only claim construction issue which was the subject of a petition for review is construction of “predetermined digital data sets” for claim 1 of the ‘880 patent. The Commission has determined to affirm the ALJ’s claim construction, and therefore agrees with the ALJ that the claim elements are met. There is no dispute that, under this claim construction, there is direct infringement of the Group I claims entirely in the United States by CCUS.³⁷ However, since the direct infringement of the method claims occurs entirely within the United States, it does not itself constitute a violation of Section 337.

See 19 U.S.C. § 1337(a)(1)(B); *Certain Electronic Devices*, Inv. No. 337-TA-724, 2012 WL 3246515, Comm’n Op. at *8–9 (Dec. 2011). We therefore examine in the next section whether there is indirect infringement by the digital data sets.

b. Indirect Infringement

i. The ID

³⁷ Joint infringement with CCPK is addressed in the section on Group IV claims, *infra*. (The ALJ found that the Group I claims are satisfied in two ways. The ALJ found that CCUS independently satisfies the Group I claims and that CCPK acts in concert with CCUS to satisfy the claims). ID at 571-72.

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The ALJ found that CCPK contributorily infringes claims 21 and 30 of the '325 patent by sending the digital data sets into the United States to CCUS. ID at 549. Similarly, the ALJ found that CCPK contributorily infringes claim 1 of the '880 patent, but did not find induced infringement of claim 1 of the '880 patent because Align did not prove specific intent. ID at 589-90.

ii. Parties' Arguments

The Respondents first argue that the ALJ applied the wrong intent standard for contributory infringement. Resp. Pet. at 55. Respondents rely on *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*), and *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2068 (2011) for the proposition that inducement requires knowledge that the induced acts constitute patent infringement. *Id.* The Respondents further note that the Supreme Court in *Global-Tech* adopted a willful blindness test for inducement. Resp. Pet. at 55-56 (citing *Global-Tech*, 131 S. Ct. at 2070). The Respondents argue that the intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement. Resp. Pet. at 56 (citing *Global-Tech*, 131 S. Ct. at 2067-68; *Aguirre v. Powerchute Sports, LLC*, 2011 WL 3359554 (W.D. Texas 2011); *Bose Corp. v. SDI Technologies Imation Corp.*, 2012 WL 2862057 (D. Mass. 2012)).

The Respondents argue that with respect to the '325 and the '880 patents, the ALJ found only that the Respondents were aware of the patents, but did not satisfy the willful blindness standard for liability. Resp. Pet. at 57. Respondents argue that the ALJ's

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finding that there was no intent to induce direct infringement should apply equally to Align's claims of contributory infringement. *Id.*

Respondents also argue that the ALJ improperly excluded evidence disproving any intent to infringe. *Id.* at 58. Respondents argue that, whether or not Align's covenant not to sue resulted in exhaustion of the patents-in-suit and liberated any acts from the possibility of infringement, Respondents' good faith belief in this defense bars a finding of culpable mens rea required for indirect infringement. *Id.*

In addition, Respondents argue that the files need only be "suitable" for a non-infringing use to avoid liability, meaning the ALJ erred in finding the files must *actually* be used for the non-infringing purpose. *Id.* (citing Robert L. Harmon, HARMON ON PATENTS: BLACK LETTER LAW AND COMMENTARY pp. 193-95 (2007)(citing *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984); *Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd.*, 545 U.S. 913 (2005))). Respondents state that the record provides examples of non-infringing uses for the digital data sets in medical research, patient evaluation, and treatment planning. *Id.* at 11-12.

Further, the Respondents argue that digital data is not "a material" or "apparatus" used in a patented process within the meaning of the statute for contributory infringement, 35 U.S.C. § 271(c). *Id.* at 60; Resps. Add. Sub. Reply at 14. The Respondents point to the text of the statute, which requires that a person supply "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process." 35 U.S.C. 271(c). The Respondents argue that the imported digital data is neither an "apparatus" nor "a material" used in a patented process, but is rather intangible information, which,

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according to Respondents, does not meet the requirements of the statute. Resps. Post-Hrg. Reply Br. at 26; Resps. Pet. at 60.

Respondents cite Black's Law Dictionary (9th ed. 2009) which defines "material" as "[o]f or relating to matter; physical . . ." Resps. Add. Sub. at 8. Respondents further argue that *Bayer's* analysis [of § 271(g)] uses the term "material" in discussing the meaning of manufacturing. *Id.* at 9 (citing 340 F.3d at 1372). Respondents note that the Supreme Court in *Microsoft* did not consider software to be a "component" under § 271(f). *Id.* at 10 (citing 550 U.S. at 451). Respondents also rely on *Veritas Operating Corp. v. Microsoft Corp.*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), which held that electronically published software could not be "a material or apparatus." *Id.* at 13-14. Respondents argue that Align's citation to *Lucent Tech.*, where the Federal Circuit rejected Microsoft's argument as being without sufficient analysis, is also without sufficient analysis. Resps. Add. Reply Sub. at 14-15 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008)). Respondents note that the three district court cases Align relies on, Align Add. Sub. at 32, were about the use of software rather than electronic transmissions of data. *Id.* at 15. Respondents assert that the alleged "products" are not software. *Id.* at 13 (citing *Eolas Techs. Inc. v. Microsoft Corp.* 399 F.3d 1325 (Fed. Cir. 2005)), but rather that the data here identifies teeth locations. *Id.* (citing ID at 19).

Align argues that the ALJ correctly found contributory infringement by CCPK. Align Resp. to Resps. at 36. Align argues that the ALJ properly applied the "Spansion" test for contributory infringement with respect to the asserted claims of the '325 patent, the '880 patent, the '511 patent, and the '874 patent. *Id.* at 36 and n.22 (citing ID at 546-

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551, 588-89, 638-39, 758-59; *Certain Elec. Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) at n.9 (citing *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010)).

Align further asserts that the ALJ “correctly applied the correct” knowledge standard for contributory infringement. *Id.* at 37. Align notes Respondents’ reliance on *DSU Med. Corp.* and *Global-Tech* for their argument that contributory infringement has a greater intent requirement than that applied by the ALJ. *Id.* Align counters that *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006), held that contributory infringement has only a “minimal intent requirement,” and that *Global-Tech Appliances, Inc. v. SEB S.A.*, only addressed the intent requirement for § 271(c) in the context of explaining that knowledge of the *existence of the patent* is required for indirect infringement under both §§ 271(c) and (b). *Id.* (citing 131 S. Ct. 2060, 2067–68 (2011)). Align concludes that the “willful blindness” test for inducement does not apply to contributory infringement. Align contests Respondents’ further reliance on two district court cases, *Aguirre* and *Bose*, for the proposition that contributory infringement requires “knowledge of the infringement” because the Federal Circuit in *Spansion*, rejected this standard and found the intent requirement for contributory infringement satisfied by presumption where there are no substantial noninfringing uses. *Id.* and n.23 (citing *Spansion*, 629 F.3d at 1355; *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) (“[o]ne who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of

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his acts; he will be presumed to intend that they shall be used in the combination of the patent”)).

Align disagrees with Respondents’ contention that the imported digital data sets have substantial noninfringing uses, actually or hypothetically. *Id.* Align asserts that Respondents’ “testimony” is directed to the vague category of “three-dimensional files”—not the specific digital data sets at issue here. Align further asserts that Respondents misconstrue the standard for showing non-infringing uses. Align argues that under Federal Circuit case law, “non-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *Id.* (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)). Align further notes that when assessing whether a use is substantial, the fact-finder may consider “the use’s frequency, … the use’s practicality, the invention’s intended purpose, and the intended market.” *Id.* (citing *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010)). Align argues that the ALJ was justified in rejecting the argument that a hypothetical use was substantial. *Id.* at 40-41 and n.27 (citing *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379–80 (Fed. Cir. 2001) (finding sufficient evidence of contributory infringement and agreeing that the jury was free to disregard the defendant’s allegation that its device had a wide range of applications to surgical procedures other than liposuction where the record did not contain any evidence of any “actual uses of the device other than ultrasonic liposuction”)). Align argues that Respondents have provided no particular evidence of any particular non-infringing use of the digital data sets, other than conclusory and speculative testimony, let alone evidence of a substantial non-infringing use. Align finally argues that not only is it conjecture that

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there are noninfringing uses, but the evidence confirms the opposite—neither CCUS nor CCPK uses the digital files for any purpose besides making aligners (Tr. at 320:24–321:2, 442:24–443:10; CX-1160C.4 at 645:15–646:4), and the digital data sets themselves are useful only to one particular patient (Tr. at 320:20–23, 443:3–6; CX-1160C.4 at 646:1–4). *Id.* at 42.

Align argues that the ALJ correctly found that digital data can contributorily infringe, *i.e.*, constitute an “apparatus” or “material” used in a patented process within the meaning of the patent statute, 35 U.S.C. §271(c). *Id.* at 42. Align argues Respondents have waived any challenge to the ALJ’s conclusion as to contributory infringement by failing to raise it in a timely fashion.³⁸³⁹ Align further argues that Respondents are mistaken on the merits because various district courts have found that digital data can contribute to infringement (within the meaning of the patent statute). *Id.* at 42-43 (citing *T5 Labs (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013) (finding sufficient pleadings that allege a ‘cloud’-based gaming application and service contributorily infringes); *Walker Digital, LLC v. Facebook, Inc.*, 852 F.Supp.2d 559, 566 (D. Del. 2012) (finding that pleadings of “software” that contributorily infringe were facially plausible); *Oracle Corp. v. Parallel Networks, LLC*, 778 F.Supp.2d 527, 544 (D. Del. 2011) (finding that specialized computer software could plausibly contributorily infringe); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F. Supp. 2d 1016, 1039 (S.D. Cal.

³⁸ Align overlooks the fact that this issue was raised by Respondents in their Post-Hearing Reply Brief. *See infra.*

³⁹ We note that this is different from the issue of whether the electronic transmission of digital data constitutes importation of an “article” within the meaning of the Commission’s statute, 19 U.S.C. §1337(a)(1)(B).

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2008) (declining to limit 271(c) to exclude software), *aff'd in part, vacated in part & remanded*, 580 F.3d 1301 (Fed. Cir. 2009)).

Align counters Respondents' argument that "digital data itself does not infringe the patents at issue" because it is not "a material or component of the aligner," and states that Respondents appear to be taking the position that a contributorily infringing article must be able to be identified in the end infringing product. Align argues that Respondents cite no precedent for such a position, that it is wrong, and that the ALJ correctly found that "the digital data sets created by CCPK are a material part of the process of creating the aligners" because the asserted claims make clear that once the digital data set(s) is (are) created, the only step remaining is to manufacture the aligners based on the digital data set(s). *Id.* at 43 (quoting *ID* at 547).

Align argues that the term "a material" in the phrase "a material or apparatus for use in practicing a patented process" in 35 U.S.C. § 271(c) may include electronic transmissions. Align Add. Sub. at 31. Align states that files placed by CCPK on CCUS's server do not differ in any meaningful way from digital files resident on CD-ROM and shipped by conventional means into the United States. *Id.* (citing *CNET Networks, Inc. v. Etilize, Inc.*, 528 F. Supp.2d 985, 994 (N.D. Cal. 2007)).

Align argues that the Federal Circuit held in *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009), that forms of data can be a "a material or apparatus," and rejected Microsoft's reliance on *Microsoft v. AT&T* for the contrary position. *Id.* at 32. Align asserts that other courts have regularly found that digital data can contributorily infringe. *Id.* (citing *T5 Labs. (Del.) LLC v. Gaikai Inc.*, 2013 U.S. Dist. LEXIS 49710 (D. Del. Apr. 5, 2013); *Walker Digital, LLC v. Facebook*,

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Inc., 852 F. Supp.2d 559, 566 (D. Del. 2012); *Oracle Corp. v. Parallel Networks, LLC*, 778 F. Supp.2d 527, 544 (D. Del. 2011)).

The IA argues that the digital data sets have no substantial non-infringing uses. IA Resp. at 15 (citing CX-1160C (J. Pumphrey) at 174:20–175:4, 645:15–646:4; CX-1162C (Rathore) at 97:1–14). The IA counters the Respondents' argument that the data sets have uses for “treatment planning and record keeping,” on the theory that record keeping is not a “use,” but something done in the ordinary course of medical and dental treatment. IA Resp. at 16.

The IA submits that the term “a material” in the phrase “a material or apparatus for use in practicing a patented process” in 35 U.S.C. § 271(c) includes electronic transmissions. The IA argues that the plain and ordinary meaning of the term “material” does not limit “material” to any specific type. *Id.* at 11. Further, the IA is not aware of any Federal Circuit opinion or Commission determination excluding electronic transmissions from being a material for use in practicing a patented process. The IA states that the Federal Circuit has affirmed district court determinations regarding contributory infringement based on the selling or offering for sale of software. *Id.* at 11–12 (citing *i4i Ltd. v. Microsoft Corp.*, 598 F.3d 831, 850–51 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320–21 (Fed. Cir. 2009)). The IA notes that there is a district court decision in which “electronically published” software was determined not to be “material” for use in a patented process, *Veritas Operating Corp. v. Microsoft*, 562 F. Supp.2d 1141, 1275 (W.D. Wash. 2008), but argues that the rationale of this case concerned the application of § 271(f) and *Microsoft v. AT&T*, and not § 271(c). *Id.* at 11 n.4.

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The IA agrees with Complainant that the term “material” in § 271(c) includes electronic transmissions. IA Add. Sub. Reply at 9 (citing *Lucent Techs., Inc.*, 580 F.3d at 1321). The IA argues that Respondents and Katz’ reliance on dictionary definitions to the contrary is misplaced because the term “material” is not properly limited to a physical article, and even if it is, the digital data sets are representative of physical articles. *Id.* at 9-10 (also citing *Lucent*).

Third-Party Submitter Andrew Katz argues that the term “material” in the phrase “a material or apparatus for use in practicing a patented process” in 35 U.S.C. § 271(c) does not include electronic transmission, Katz Sub. at 16, relying primarily on dictionary definitions of “material.” *Id.* at 16-17. Mr. Katz further asserts that the analysis of components in *Microsoft*, a case decided under § 271(f), is analogous to the analysis of components under § 271(c), and that *Microsoft* held that electronically transmitted software was not a component under § 271(f). *Id.* at 17-18.

Third-Party Submitter Nokia argues that both Supreme Court and Federal Circuit precedent establish that electronic transmissions can qualify as infringing “components” or “materials or apparatus” under 35 U.S.C. § 271(c), as well as be the subject of certain induced infringement claims under 35 U.S.C. § 271(b), and thus also constitute articles within the meaning of Section 337. Nokia Reply Sub. at 1. Nokia asserts that the third party arguments with respect to *Suprema* are beyond the scope of the questions posed by the Commission, and in any event mischaracterize *Suprema* because *Suprema* reaffirmed that contributory infringement is a valid basis for a violation of Section 337. *Id.* at 2.

Nokia further argues that electronic transmission of software can be a “component” or a “material or apparatus” under § 271(c). Nokia Reply Sub. at 3. Nokia

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argues that the Federal Circuit has never squarely held that electronically transmitted software is a “material or apparatus” but its rulings strongly support that notion in holding that software may be a “material or apparatus.” *Id.* at 3-4 (citing *i4i*, 598 F.3d at 850-51 and *Lucent*, 580 F.3d at 1320). Nokia further argues that *Microsoft v. AT&T* supports the notion that electronically transmitted software is a “material or apparatus” because the Court differentiated between “software in the abstract” and a “tangible” copy of software, as on a CD-ROM. *Id.* at 5 (citing 550 U.S. at 448). Nokia quotes the Supreme Court’s statement that “[u]ntil it is expressed as a computer-readable ‘copy,’ e.g., on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable.” *Id.* at 5-6 (citing 550 U.S. at 449). Nokia concludes that the “key inquiry in *Microsoft*” is whether software was available in a form in which it was combinable to form the patented invention. *Id.* at 6.

iii. Analysis

Contributory infringement is set forth at 35 U.S.C. § 271(c), which provides as follows:

- (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

See 35 U.S.C. § 271(c).

Specifically with respect to Section 337 investigations, the Federal Circuit has held that “to prevail on contributory infringement in a Section 337 case, the complainant

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must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement.”

Spansion, Inc. v. Int'l Trade Comm'n, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

With respect to the intent element of Section 271(c), the contributory infringement statute requires that the infringer knows that the patented component is specially adapted for infringement and that there are no substantial noninfringing uses. See 35 U.S.C. § 271(c). Recent cases have explained that the intent requirement for contributory infringement is knowledge of the patent. *Spansion*, 629 F.3d at 1353. The Court has explained that this is based on a presumption that the intent requirement is satisfied where there are no substantial noninfringing uses for the component. *Id.*

The ALJ found that Respondents had knowledge of the '325 and '880 patents. ID at 549, 589. We affirm this finding. The ALJ also noted Respondents' admission that “digital data sets and treatment plans are not bought and sold. *They are essentially instructions for making physical aligners. They have no separate commercial value.*” ID at 548 (emphasis in ID). This statement is evidence of no substantial non-infringing uses and may also be evidence that Respondents acted “knowing the same to be specially adapted for their infringing use.” See 35 U.S.C. § 271(c).⁴⁰ We affirm the ALJ’s finding of no substantial non-infringing use. ID at 548. Therefore, we find that CCPK possessed the requisite intent for contributory infringement.

⁴⁰ The Respondents argue, as a defense, that they believed in good faith that they had an implied license to practice the patents in suit. However, this defense rises and falls with the implied license defense, which we determined is waived. We therefore conclude that Respondents possessed the requisite intent for contributory infringement.

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Next we address whether the digital data sets are “a material or apparatus” within the meaning of § 271(c). To begin we determine that Respondents’ argument that digital data is not an “apparatus” or “a material” was not waived because there was no requirement for Respondents to assert a defense before their brief in reply to Align’s opening post-hearing brief. *Cf.* Ground Rules 8.2 and 11.1. The burden is on Align to establish all elements of its allegation of contributory infringement, and the defense here is not an affirmative defense, but rather a statement that complainant has failed to make out the elements of its case.

Align does not argue that an electronically transmitted data set can be an “apparatus.” Rather, Align contends that the accused digital data sets are either a material or component within the meaning of Section 271(c).

We consider whether the term “a material” connotes something tangible which might pertain to whether the digital data at issue here are encompassed within the meaning of this statutory term. In assessing the meaning of this term, we first look to contemporaneous dictionary definitions. The word “material” has long had a widely accepted definition as an input into a more finished work. For example, Webster’s defines material to include “[d]ata of any sort, such as notes, documents, sketches, etc., which may be worked up into a more finished form; as *materials* for a biography; hence, facts, perceptions; ideas, etc., viewed as data for a further operation; as the raw *material* of experience.” *Id.*⁴¹ This common meaning of the term “material” is reflected in a plurality of dictionary definitions. *See, e.g.*, FUNK & WAGNALLS NEW STANDARD

⁴¹ *Accord* Webster’s New Collegiate Dictionary (1979) (defining “material” as “data that can be worked into a more finished form.”).

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DICTIONARY OF THE ENGLISH LANGUAGE (1940) (“Collected facts, impressions, or ideas or notes containing them, and sketches, etc., that may be used in completing a literary or an artistic production; as *material*, for a sermon”); THE WINSTON DICTIONARY: COLLEGE ED. (1942) (“data, as notes and sketches, for further elaboration; as material for a speech; that which may be worked up into other forms or for other purposes”);⁴² THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE. (1952) (“Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, “the materials of seditions,” Bacon’s “Essays,” Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)).⁴³

Furthermore, in law, as well as in many of the humanities and social sciences, it has long been very common for the content of some text or statement to be referred to as the “material” that was being conveyed. For example, it would be well within ordinary usage for a speech writer looking for famous quotes to refer to them as source “material;” and it likewise would be well within ordinary usage for someone who attends a lecture to use the word “material” when referring to the content of the lecture rather than to any physical props, visual aids, instruments, or costumes. Indeed, the Supreme Court in *International News Service v Associated Press*, 248 US 215 (1918), used the word “material” several times in its opinion referring to the misappropriation of the content

⁴² Accord NEW OXFORD AMERICAN DICTIONARY (3rd ed. 2010) (defining “material” as “facts, information, or ideas for use in creating a book or other work . . .”).

⁴³ Accord WEBSTER’S NEW COLLEGiate DICTIONARY (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).

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contained in fresh news transmitted electronically. 248 US 239 (“defendant...admits that it is taking material that has been acquired by complainant...”). Such intangible materials have also been the linchpin of well known contributory infringement cases for well over 100 years. *See, e.g., Kalem Co. v. Harper Brothers*, 222 U.S. 55 (1911) (contributory infringement of copyright in the book Ben Hur) (Holmes, J.); *Gershwin Pub. Corp. v. Columbia Artists Management*, 443 F.2d 1159 (2nd Cir. 1971) (contributory infringement of copyrights in music); *Screen Gems-Columbia Music v. Mark-Fi Records*, 327 F.Supp. 788 (SDNY 1971) (same).

Other definitions of “a material” do relate to physical matter. *See, e.g., BLACK’S LAW DICTIONARY* (4th ed. 1951) (defining “materials” as “the substance or matter of which anything is made”).⁴⁴ *See also WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE* (2d. ed. 1948) (defining “material” as “the substance, or substances, or the parts, goods, stock, or the like, of which anything is composed or may be made . . . material things.”)⁴⁵ *See also THE NEW CENTURY DICTIONARY OF THE ENGLISH LANGUAGE*. (1952) (“Material (n): the substance or substances of which a thing is made or composed; any constituent element of a thing; often, anything serving as crude or raw matter for working upon or developing (as, “the materials of seditions,” Bacon’s “Essays,” Of Seditions and Troubles; the materials of a history or drama); also, a textile fabric; also, pl., articles of any kind requisite for making or doing something (as, writing-materials)). But none of these definitions that relate to physical matter suggest they

⁴⁴ Contemporary editions are in accord. *See, e.g., BLACK’S LAW DICTIONARY* (9th ed. 2009), (defining “material” as “[o]f or relating to matter; physical . . . ”).

⁴⁵ *Accord Webster’s New Collegiate Dictionary* (1979) (defining “material” to be “the elements, constituents, or substances of which something is composed.”).

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would preclude the other definitions discussed earlier that do not relate to physical matter.

There is no controlling case law construing “a material” in § 271(c) in this factual context, but there are a number of court decisions that are instructive. There are two Federal Circuit cases which involve an allegation that the provision of software satisfied the requirement for contributory infringement, but it does not appear in either case that the involved software was electronically transmitted. Both cases were presented to the Court on review of jury verdicts finding contributory infringement. The first case is *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed. Cir. 2009). In that case, Lucent argued that Microsoft’s software product, a calendar “date-picker” tool, contributorily infringed a method for displaying information in fields covered by its ‘356 patent. Microsoft argued that the “material or apparatus” was the entire Outlook software package, which had substantial non-infringing uses. The Court rejected this argument because the specific feature, the date-picker tool, was suitable only for the infringing use covered by the method claims and that inclusion within the larger Outlook program did not change the date-picker’s ability to infringe. *Id.* at 1321. In so ruling, the Court observed that “if, instead of selling Outlook with the date-picker, Microsoft had offered the date-picker for sale *as a separate download* to be used with Outlook, there would be little dispute that Microsoft was contributing to infringement of the Day patent.” *Id.* at 1320 (emphasis added). Thus, the Court appeared to suggest that electronic transmissions of software would fall within at least one of the statutory categories of “a material or apparatus” and thereby provide a basis for contributory infringement.

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Microsoft also argued on appeal that its software product was not a “material or apparatus” under 35 U.S.C. § 271(c), based on the Supreme Court’s decision in another case involving Microsoft, *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437 (2007). In *Microsoft*, the Supreme Court held that the export of a “golden disk” of software did not constitute export of a “component” under a different provision of the patent statute, 35 U.S.C. § 271(f). The *Lucent* Court, noting that Microsoft relied on *Microsoft* “without further analysis,” held that the Supreme Court in *Microsoft* did not address the issue of what constituted a material or apparatus for purposes of 35 U.S.C. § 271(c), and *Lucent* did not comment on the issue further.⁴⁶

In the lower court, the issue was framed in terms of “component” rather than “a material or apparatus,” with Microsoft relying on the Supreme Court’s decision in *Microsoft*. The lower court rejected that argument because the Supreme Court did not purport to reach 35 U.S.C. § 271(c). The lower court also noted that “The dispute over the ‘356 patent involves method claims and commercial sales of software copies, not apparatus claims and foreign distribution of software ‘in the abstract.’” *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.Supp.2d 1016, 1039 (S.D. Cal. 2008) (citing *Microsoft*, 127 S. Ct. at 1727, as “distinguishing the abstract software code at issue from computer-readable copies, such as those ‘inserted into a CD-ROM drive or downloaded from the Internet’”). Thus, it appears that the district court distinguished the computer readable Outlook software copies in the *Lucent* dispute as substantively distinct from software “in the abstract” that was involved in the *Microsoft* case. As noted above, the Supreme

⁴⁶ See also *Arris Group, Inc. v. British Telecommunications PLC*, 639 F.3d 1368 (Fed. Cir. 2011) (citing *Lucent* and finding an Article III case or controversy exists arising from allegations of contributory infringement).

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Court's analysis in *Microsoft* indicates that for Section 271(f), software cannot be a component of a patented invention until it is in a form that can be installed or executed on a computer, *i.e.*, on a CD or downloaded from the internet. 550 U.S. at 449, 451, but is not dispositive of the meaning of "a material or apparatus" under § 271(c) as it was decided under § 271(f), and turned on the particular text and legislative history of that subsection of Section 271, which are different than those for subsection c.

The other Federal Circuit case is *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010). In that case, i4i's '449 patent claimed an improved method for editing documents containing mark-up languages like XML. i4i sued Microsoft for infringement by making, using, selling, offering to sell, and/or importing Word products capable of processing or editing Custom XML. A jury found Microsoft guilty of willful infringement. i4i presented three theories of liability: direct, contributory, and induced infringement. The jury returned a general verdict which did not require separate findings on the different theories. On appeal, Microsoft argued the trial judge erred in his contributory infringement instructions because he used the term "component" rather than "material or apparatus." The Federal Circuit rejected that argument, stating that the difference in language did not make a difference in that case, noting that the parties' used the terms interchangeably and their argument had not turned on whether Word's XML editor was a "component" rather than a "method or apparatus." The Court concluded that "there was sufficient evidence before the jury for it to conclude that the relevant 'material or apparatus' was the custom XML editor, not all of Word." *Id.* at 849.

In *Ricoh Co., Ltd. v. Quanta Computer, Inc.*, 550 F.3d 1325 (Fed. Cir. 2008), the Court held that the sale of software containing instructions to perform a patented method

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does not infringe a patented method under 35 U.S.C. § 271(a). The Court compared the situation to *Microsoft v. ATT*, which it cited for the proposition that “software is not a component of a patented device within the meaning of 35 U.S.C. § 271(f) until it is reduced to a machine-readable copy.” *Id.* at 1335 (citing *Microsoft*, 127 S. Ct. at 1753-55).

Further, there is one district court case which held that electronic copies of software did not constitute “a material or apparatus,” based on *Microsoft v. AT&T*. See *Veritas Operating Corp. v. Microsoft Corp.*, 562 F.Supp.2d 1141, 1275 (W.D.Wash. 2008). On the other hand, as Align notes, a California district court held that an electronic catalog was a physical “product” within the meaning of Section 271(g) finding *Microsoft v. AT&T* instructive on this point:

In *Microsoft*, the issue before the court was whether software is a combinable “component” for purposes of section 271(f). [127 S.Ct.] at 1755. The court stated that software “abstracted from a tangible copy” is simply abstract information. *Id.* Only when expressed and stored as machine-readable object code, e.g. burned on a CD-ROM or written to a server hard drive such that it is capable of being downloaded from the internet, does software become an actual, physical component amenable to combination. *Id.* at 1756. The court held that “a copy of Windows [software], not Windows in the abstract, qualifies as a ‘component’ under § 271(f).” *Id.*

CNET Networks, Inc. v. Etilize, Inc., 528 F. Supp.2d 985, 994 (N.D. Cal. 2007).

Thus, the *Lucent* and *i4i* cases involve contributory infringement of software in a combinable form, which provide some indication as to whether digital data sets that are at issue here may be considered to contributorily infringe under Section 271(c). The Supreme Court’s decision in *Microsoft* is instructive that software cannot be a “component” under § 271(f) unless it is in a form that can be read by and combined with

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a computer regardless of whether it is “delivered by CD-ROM or some other means capable of interfacing with the computer,” 550 US at 451, but is not dispositive of the meaning of “a material or apparatus” under § 271(c) as it was decided under § 271(f).

In addition, the Commission has previously found contributory infringement with respect to software that meets certain method steps in *Hardware Logic*. Inv. No. 337-TA-383, 1997 WL 665006, ID at *94. The Commission determined not to review the ID and thereby found a violation of Section 337. Notice (Oct. 2, 1997). The involved software was imported both on a CD and via electronic transmission. *Id.* at * 95. However, the issue of whether the software was a “material or apparatus” under Section 271(c) was not raised in that investigation.

In view of the guidance from these courts and these definitions, we affirm the ALJ’s finding of contributory infringement of the Group I claims because electronic transmissions of digital data qualify as “a material or apparatus” within the meaning of 35 U.S.C. § 271(c).⁴⁷

⁴⁷ This conclusion applies to all contributory infringement allegations in this investigation.

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2. Group II Claims (Claims 31 and 32 of the ‘325 patent⁴⁸; Claims 1 and 4-8 of the ‘863 patent; Claims 1, 3, 7, and 9 of the ‘666 patent; Claims 1, 3, and 5 of the ‘487 patent)

The Group II claims are directed to methods of generating digital data sets. The digital data sets at issue here are generated by CCPK in Pakistan prior to their electronic transmission to the United States. *See* ID at 472-73. Specifically, CCPK provides the initial data set it obtains from CCUS to the CCPK computer platform and manipulates the data set into final and intermediate positions. It is alleged that CCPK’s process of generating final and intermediate data sets in Pakistan practices the Group II claims, and the subsequent transmission of the generated data sets to CCUS constitutes a violation under Section 337(a)(1)(B)(ii). That provision concerns violations related to the importation of articles “made, produced, processed, or mined” using a process covered by a U.S. Patent.

a. The ID

For the ‘325 patent, the ALJ found that CCPK independently practices claims 31 and 32. ID at 512-13, 514-15. As to the ‘863 patent, the ALJ found that CCPK practices claim 1. ID at 694-97. The ALJ further found that CCPK practices dependent claims 4-8 in Pakistan by producing the digital data sets. ID at 709, 714, 722, 725, 729. As to the ‘666 patent, the ALJ found that CCPK practices claims 1, 3, 7, and 9. ID at 655, 659,

⁴⁸ Align includes these claims in both Group II and Group IV. Align includes the claims in Group II because the ALJ found that CCPK independently infringes when it produces the digital data sets abroad and provides them to CCUS. ID at 512-13. The ALJ also found that CCUS provides the data sets to a computer, which would place the claims in Group IV. *Id.* (The ALJ did not make a factual finding that CCPK and CCUS therefore infringe in concert but that appears to be the implication.) As noted in our claim construction section, we understand “provide” to include conveying by electronic transfer. Therefore, these claims can be analyzed with CCUS as the sole infringer when it electronically transfers the data to the computer and also with CCPK as a joint infringer when it electronically transfers the data set to CCUS.

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666, 669. As to the ‘487 patent, the ALJ found that CCPK practices claims 1, 3, and 5. ID at 607, 609, 612.

The ALJ found the Respondents imported digital data sets that were made in Pakistan using the entire process of the Group II claims. Based on this, he concluded that Respondents violated 19 U.S.C. § 1337(a)(1)(B)(ii). *See* ID at 550, 624, 670, 732. We affirm, adopting the ALJ’s analysis finding that the claim limitations are met. We analyze the other requirements of Section 337 as follows.

b. Parties’ Arguments

The Respondents have argued that the requirements of Section 337(a)(1)(B)(ii) are not met, *i.e.*, that there is no article that is “made, produced, processed, or mined” within the meaning of the statute as part of their arguments that there is no “article.” Respondents point out that the Federal Circuit used the term “processes” as part of its analysis in *Bayer* that held that a physical product is required under Section 337 or § 271(g). Resps. Add. Sub. at 7.

Align argues that the plain meaning of “processed” must include “data processing on a computer.” Align Add. Sub. at 17. Align reports the following dictionary definitions of the verb “process,” *inter alia*; “to prepare by or subject to a special process or method” (WEBSTER’S NEW WORLD DICTIONARY (1988) (where the noun “process” means a particular method of doing something, generally involving a number of steps or operations); “to treat or prepare by some particular process, as in manufacturing” (RANDOM HOUSE DICTIONARY (1987) (where the noun “process” means “a systematic series of actions directed to some end”). Align states that none of these definitions is limited to processes that use physical items. *Id.* at 18. Align continues that contemporary

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dictionary definitions and dictionary definitions contemporaneous with the enactment of [the process patent provision of] Section 337(a) in 1940 are similar. *Id.* at 18-19.

Align suggests that “processed” and “process” in subsection (ii) [of Section 337(a)(1)(B)] must be given the same meaning, and must be coextensive with any patented process. *Id.* at 20. Align argues that the close proximity of these terms in the statute provides a strong indication that they should be accorded the same meaning, and the meaning of either should inform the other. *Id.* at 20 (citing *Hall v. United States*, 132 S. Ct. 1882, 1891 (2012); *Brown v. Gardner*, 513 U.S. 115, 118 (1994)). Align concludes that “process” refers to any process that is claimed in a valid and enforceable U.S. patent, and that “processed” refers to the use of any patented process. *Id.* at 20.

Align further reasons that because “articles” may be digital data, subsection (ii) must contemplate processes that create digital data. *Id.* at 21. Align argues that a statutory term must be read in its context and with a view to its place in the overall statutory scheme. *Id.* at 21 (citing *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 644 (Fed. Cir. 2011) (citing *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 809 (1989)); *King v. St. Vincent’s Hosp.*, 502 U.S. 215, 221 (1991)); see also *id.* at 22 (citing cases for the proposition that terms in related provisions have similar interpretations).

Align asserts that the term “process” as used in Title 35 includes data processing, and that is informative here. *Id.* at 22. Align argues that the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972), interpreted the term “process,” which is defined in 35 U.S.C. § 100(b), to mean “a mode of treatment of certain materials to produce a given result. It is an act or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Id.* at 23 (quoting *Gottschalk*

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(quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).⁴⁹ Align urges that data processing satisfies this definition because it is “an act” or “a series of acts.” *Id.* Align argues that “process” in § 271(c) and (g) also includes data processing. *Id.* at 24-24. With respect to § 271(g), Align relies on *CNET*, 528 F. Supp.2d at 993, which distinguishes *Bayer*, and explains that a data file is a product of a patented process where practicing each step of the method leads directly to the creation of the [data file]. *Id.* at 25.

Align argues that precedent confirms a broad reading of subsection (ii). *Id.* at 26. Align remarks that the Federal Circuit has referred to Section 337 as conferring rights on “process patent holders” and not on a subset thereof. *Id.* (citing *Kinik Co. v. ITC*, 362 F.3d 1359, 1362-63 (2004); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012)). Align relates that the Commission’s references to the process patent provision are in accord. *Id.* at 26 (citing *Certain Methods of Making Carbonated Candy Products*, Inv. No. 337-TA-292, Notice of Termination (March 8, 1990); *Certain Plastic Encapsulated Integrated Circuits*, Inv. No. 337-TA-315, 1992 ITC LEXIS 738, n.138 (Nov. 1992)).

Align asserts that the legislative history of Section 337 dictates that “processed” include the practice of all types of patented process claims, although Align maintains that there is no need to consult the legislative history because of the plain meaning of the term. *Id.* at 27 (*Darby v. Cisneros*, 509 U.S. 137, 147 (1993)). Align relates how the process patent amendment to Section 337 was intended to overrule the CCPA’s decision

⁴⁹ We note that the Court in *Gottschalk* ultimately decided not to resolve whether computer programs were patentable, instead leaving the question to Congress. 409 U.S. at 72-73.

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in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), and how a Congressional proponent of the legislation explained that it would include “all of the products and articles and the importation of articles produced on which there is a patent.” 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29. Align argues that the legislative language was directed to the practice of any process covered by a valid and enforceable U.S. patent, and was not meant to otherwise limit the scope of the provision. *Id.* at 30.

The IA submits that the term “processed” in Section 337(a)(1)(B)(ii) includes data processing by a computer. IA Add. Sub. at 9. The IA argues that neither the plain language nor the legislative history of the statute supports limiting the term “processed” to any specific type of processing, much less excluding data processed by a computer. *Id.*

The IA further argues that the plain language of the statute distinguishes articles that are “processed” from three other types of articles (i.e., articles that are “made,” articles that are “produced,” and articles that are “mined.”) *Id.* The IA argues that the plain and ordinary meaning of “processed” includes “data processing,” and that a claim for a process may include data processing by a computer. *Id.*

The IA asserts that the legislative history also supports interpreting the term processed in this manner, and that nothing in the legislative history supports a limiting construction. *Id.* at 10 (citing *Amgen v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990)).

The IA agrees with Complainant that “processed” in Section 337(a)(1)(B)(ii) includes data processing in view of *Gottshalk v. Benson*, 409 U.S. 63, 70 (1972), discussing the term “process” in the patent context, and *Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012), discussing the process patent provision of Section 337. IA Add. Sub. Reply at 8. The IA asserts that Katz’s reliance on *Bayer* and *NTP* for

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the meaning of “processed” in Section 337 is misplaced because those cases interpret § 271(g) rather than Section 337. *Id.* at 8-9.

Mr. Katz argues that the term “processed” in Section 337(a)(1)(B)(ii) does not include data processing by a computer. *Id.* at 15. Mr. Katz reasons that “processed” cannot include data processing by a computer where data is the only product because data, information, and electronic transmissions do not qualify as articles under *Bayer* and *NTP*. *Id.* at 16. Mr. Katz argues that the court in *Bayer* held that § 271(g) was “concerned solely with physical goods that had undergone manufacture” and “for a product to have been ‘made by a process patented in the United States’ it must have been a physical article that was ‘manufactured’ and that the production of information is not covered.” *Id.* at 16 (quoting *Bayer*, 340 F.3d at 1373; also citing *NTP*, 418 F.3d at 1323-24).

c. Analysis

Section 337(a)(1)(B)(ii) provides as follows:

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

...
 (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--

...
 (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337.

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We assess whether data processing results in something “processed” within the meaning of the statute.

The four statutory terms in the list of Section 337(a)(1)(B)(ii), “made, produced, processed, or mined,” represent four different kinds of methods by which goods are created. “Made” is the past participle of “to make” which means “to produce by a combination of parts, or by giving a certain form to a portion of matter; to construct, frame, fashion, bring into existence.”⁵⁰ SHORTER OXFORD ENGLISH DICTIONARY (1933). Something that is “made” thus has the meaning of having been assembled or shaped. “Produced” is the past participle of “to produce” meaning “to compose or bring out (a work of literature); to work up from raw material (material objects).” *Id.* Something that is “produced” is therefore composed or worked. “Processed,” the term in question, is the past participle of “to process” which means “2. to treat by a special process; e.g., to reproduce (a drawing, etc.) by a mechanical or photographic process.” *Id.* The noun form of “process,” in turn, means “6. A continuous and regular action or succession of actions taking place or carried out in a definite manner. . . b. A particular method of operation in any manufacture. . . ” *Id.*⁵¹⁵² These definitions support the conclusion that

⁵⁰ The Federal Circuit in *Bayer* found “made” in § 271(g) to mean “manufactured.” See *Bayer*, 340 F.3d at 1372.

⁵¹ Other contemporaneous dictionaries are in accord. See WEBSTER’S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (2d. ed. 1937) (“2. To subject to some special process or treatment. . . b. To subject (esp. raw material) to a process of manufacture, development, preparation for the market, etc.; to convert into marketable form. . . c. To make usable, marketable, or the like. . . d. To produce or copy by photomechanical methods; to develop, fix, wash, and dry, or otherwise treat”); FUNK & WAGNALLS NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE (1938) (“2. To produce, as illustrations, by a process, especially by photoengraving: used chiefly in the past participle. 3. To treat by a process; specif. to heat, by steam or otherwise, so as to cook or sterilize”).

⁵² Modern, contemporary definitions are in accord. In fact, the Sixth Edition (2007) of the SHORTER OXFORD ENGLISH DICTIONARY has an example relating to data as a specific case of the generic definition: “Subject to or treat by a process or in a processor; spec. (a) reproduce . . . (b) preserve . . . (c) operate on (data) using a computer; (d) puree or liquidize (food) in a food processor....”

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“processed” is the result of treatment or change through a fixed series of actions.

“Mined” refers to extraction from the earth. *Id.*

Thus, the term “processed” refers to something that has been subjected to a treatment or change according to a series of actions, in contradistinction to “made” which generally refers to something assembled from parts and in contradistinction to “produced” which generally refers to something that is “composed” (if it is a literary composition) or “worked” (if it is a material object). These are all ways that something may be the result of a patented process. Thus it appears that by using the phrase “made, produced, processed, or mined under, or by means of a process covered by the claims of a valid and enforceable United States patent,” Congress was trying to comprehensively cover all ways in which a method patent can be infringed.

The legislative history is consistent with this understanding of the statute. Section 337(a)(1)(B)(ii) is the reenactment of former Section 337a. Congress explicitly gave the Commission this jurisdiction in 1940 to overturn the CCPA’s decision in *In re Amtorg*, 75 F.2d 826 (CCPA 1935), where the Court held that the importation of a phosphate rock mined abroad by a process that was patented in the United States did not constitute an unfair trade practice. The legislative report states that “Since the Amtorg decision owners of American process patents are helpless to prevent the infringement abroad of their patent rights. This bill will give to them the same rights which the owners of product patents have.” S. Rep. 76-1903 at 4 (1940) (no emphasis in original). Moreover, the language of the amendment and this legislative history indicate that the legislation was not limited to the mining of phosphate rock at issue in *Amtorg*, but rather was intended to cover the full range of activity that may be covered by a patented process --

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“made, produced, processed, [and] mined.” This is in keeping with prior Commission cases under the Tariff Act of 1922 and 1930.⁵³ Indeed, one Congressman explained that Section 337a would include “all of the products and articles and the importation of articles produced on which there is a patent.” 86 Cong. Rec. H3783 (daily ed. Apr. 1, 1940) (statement of Rep. Wolcott). *Id.* at 29.

Commission cases are in accord with the understanding that “processed” means treated. For example, in *Sucralose*, without differentiating between “made, produced,

⁵³ Section 337a was intended to overrule *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), and to reinstate two prior CCPA decisions, *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930) and *Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

In *Synthetic Phenolic Resin, Form C, and Articles Made Wholly or in Part Thereof* the Commission, under the Tariff Act of 1922, found unfair methods of competition in the importation of synthetic phenolic resin, Form C, and articles made wholly or in part thereof made abroad using patented processes. U.S. Tariff Commission, Report No. 3, at 15 (1930). One of the patents covered a method for making synthetic phenolic resin, Form C, and another covered a method of fusing synthetic phenolic resin material, Form C, together including material of different colors. In each case, the direct result of the patented process was a material which could then be used to make various articles, such as the imported products. The Commission recommended that the President issue an exclusion order, based in part on the recited process claims. The Court of Customs and Patent Appeals subsequently affirmed the Commission. *Frischer & Co. v. Bakelite Corporation*, 39 F.2d 247 (CCPA 1930), cert. denied sub nom. *Frischer & Co. v. Tariff Commission & Bakelite Corporation*, 282 U.S. 852 (1930).

In *Oxides of Iron Suitable for Pigment Purposes*, Inv. No. 337-4 (Tariff Commission 1934)), the Commission, under the original Section 337 of the Tariff Act of 1930, found unfair methods of competition in the importation of iron oxide pigment made from iron ore using patented processes. The Commission recommended issuance of an exclusion order covering the subject imports: a yellow pigment directly produced by the patented process and a red pigment which was a dehydrated form of the yellow pigment. The Court of Customs and Patent Appeals subsequently affirmed the Commission in *In re Northern Pigment Co.*, 71 F.2d 447, 22 CCPA 166 (1934).

The Commission followed *Iron Oxides in Phosphate Rock*, Inv. No. 337-3. Tariff Commission 17th Annual Report at 41 (1933) and 18th Annual Report at 41 (1934). In that investigation, the Commission found unfair methods of competition based on the importation of phosphate rock or apatite which had been processed (concentrated) by a method covered by the claims of two patents. The imported phosphate rock appears to have been the direct product of the patented process. The Court of Customs and Patent Appeals subsequently reversed the Commission’s determination in *Phosphate Rock* in *In re Amtorg*, 75 F.2d 826, 22 CCPA 558 (1935), thereby also overruling *Northern Pigment* and *Frischer*.

After conducting hearings on the impact of *In re Amtorg* in 1938, Congress passed former section 337a (former 19 U.S.C. § 1337a) to overrule that decision, providing:

The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

54 Stat. 724 (July 2, 1940). This statute was intended to overrule the CCPA’s decision in *In re Amtorg*.

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[or] processed,” the Commission found that the chemical treatment or transformation of sucrose to sucralose by the substitution of chlorine atoms for hydroxyl groups satisfied the requirements of Section 337(a)(1)(B)(ii). Similarly, data processing can infringe a method claim in the United States under 35 U.S.C. § 271(a). *See, e.g., SiRF Technology, Inc. v. ITC*, 601 F.3d 1319, 1329 (Fed. Cir. 2010) (a method of receiving global positioning system (GPS) satellite signals). Further, a claim for a process may include data processing by a computer where the claim is not directed to a purely abstract idea. *See Bilski v. Kappos*, 130 S. Ct. 3218, 3228-29, 3231 (2010) (discussing business method patents). Accordingly, the Commission agrees with Align and the IA that the plain meaning of “processed” includes data processing on a computer. This is the plain meaning in modern parlance, and is consistent with the historical meaning of “process” as a mode of treatment, as explained below.

As we explained in detail above, the *Bayer* case, relied on by Respondents, interpreted the meaning of 35 U.S.C. § 271(g). The meaning of Section 337 was not directly before the Court in *Bayer*. To the extent it commented on Section 337(a)(1)(B)(ii), it addressed the term “made” which appears in § 271(g). Consistent with this definition, the Court in *Bayer* found “made” in § 271(g) to mean “manufactured.” It did not address the meaning of “processed” in Section 337. *Bayer*, 340 F.3d at 1372. As *Bayer* states, the language of Section 337 indicates that it has a broader scope than § 271(g). *Id.* at 1374 n.9. *Bayer*, in construing the term “made,” concluded that information in that case was not “made.” *Id.* at 1371. However, while § 271(g) may be limited to products that are “made,” Section 337 may be broader in scope because it also covers articles that are “processed” and “mined” (and perhaps also

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“produced” depending on the sense of the word). Further, even to the extent that the process patent jurisdiction of Section 337 is similar to that of § 271(g), the obtaining of the information in *Bayer* is different than the “process[ing]” of the digital data sets representative of teeth here. In *Bayer*, the information was obtained by applying substances to cell lines in order to determine whether the agent is an inhibitor or an activator. *Id.* at 1369. That was simple information because the agent was either an inhibitor or an activator. However, here the digital data sets are more complex, are directly representative of teeth, and are “processed” or treated through a series of interpolations, in a manner analogous to physical manipulation of a mold of teeth. Indeed, Respondents have argued in defense to violation that the claimed processes are anticipated or rendered obvious by physical analogs from the 1940s. *See, e.g.,* Resps. Sub. at 12. While we do not find that the prior art taught the same interpolation technique, we find that the art of processing of the digital data is analogous to the art of processing of plaster casts of teeth which had been physically manipulated since at least the 1940’s in the treatment of patients. *See U.S. Patent No. 2,467,432.* The digital data set of teeth is treated or manipulated in the same manner as a plaster cast of teeth.

We therefore conclude that digital data are “articles” that are “processed” within the meaning of Section 337(a)(1)(B)(ii). Because CCPK practices the method of the Group II claims, CCUS and CCPK satisfy the elements of Section 337(a)(1)(B)(ii) in the sale for importation, importation, and sale after importation of the subject digital data sets and treatment plans.

PUBLIC VERSION**3. Group III Claims (Claims 7-9 of the '487 patent)**

The Group III claims are directed to treatment plans (*i.e.*, a series of digital data sets) on a storage medium.

a. Direct Infringement**i. The ID**

The ALJ found that the intermediate digital data sets produced by CCPK meet each and every limitation of claim 7 when they are stored on CCPK or CCUS computers, servers, or other forms of “computer readable storage media.” ID at 616. However, the ALJ proceeded to analyse the activity with respect to the requirements of Section 337: “This does not, however, end the inquiry. The Commission has explained that “section 337(a)(1)(B)(i) covers imported articles that directly or indirectly infringe when it refers to ‘articles that -- infringe.’ *We also interpret the phrase ‘articles that – infringe’ to reference the status of the articles at the time of importation.* Thus, infringement, direct or indirect, must be based on the articles as imported to satisfy the requirements of section 337.” ID at 619 (quoting *Certain Electronic Devices With Image Processing Systems, Components Thereof, And Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Dec. 21, 2011) (emphasis in ID)).” The ALJ found that at the time of importation, the accused digital data sets do not meet each and every limitation of claim 1 and thus do not directly infringe that claim because they are electronically transmitted and thus do not reside on “storage media,” as required by the claims, at the time of importation. ID at 619. Because the ALJ found no direct infringement of claim 7 at the time of importation, he found no direct infringement of dependent claims 8 and 9. ID at 620, 622.

ii. Parties' Arguments

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Align argues that Respondents waived their noninfringement arguments because these arguments did not appear in their pre-hearing brief, but appeared for the first time in their post-hearing brief. Align Pet. at 7. Align argues that the ALJ therefore abused his discretion in finding no infringement. *Id.*

Align also argues that there is a sale for importation, *i.e.*, CCPK sells its data sets to CCUS, and that at the time this sale occurs, the data sets are residing on CCPK's storage medium. *Id.* at 8-9. Align further argues that the act of importation includes the act of putting the electronically transmitted data on a storage medium. *Id.* at 9. Align further asserts that the policy underlying the 724 decision is not implicated here because this is not a situation where, as there, an imported article arrives in a non-infringing state and is later transformed into an infringing article by some separate post-importation step such that it would not be fair to say that the product infringes "as imported." *Id.* at 10.

The Respondents respond that neither the workstation nor the computer is imported. Resps. Resp. at 3. The Respondents argue that it does not matter whether there is a sale for importation or sale after importation because the law, as embodied by the 724 decision, requires infringement at the time of importation. *Id.* at 4.

The IA argues that Respondents waived their non-infringement arguments because they were not included in the pre-hearing brief. IA Resp. at 4. However, to the extent that the arguments were not waived before the ALJ, the IA agrees with Respondents. *Id.* at 4-6.

iii. Analysis

The Commission affirms and adopts the ALJ's finding that there is no direct infringement of the Group III claims at the time of importation, as set forth in the ID at

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617-623. In raising certain non-infringement arguments for the first time in their post-hearing brief, Respondents did fail to comply with ALJ's Ground Rule 8.2, which requires that all arguments appear in the pre-hearing brief. Although the ALJ would have been entitled to find waiver based thereon, his decision not to do so is generally reviewed for abuse of discretion and for whether it is contrary to law. *Cf.* 19 C.F.R. §210.43 (standard for petition for review). The ALJ in his management of the case considers the interests of justice, prejudice to the parties, and whether a finding of violation of Section 337 would be contrary to law. Here, the ALJ chose not to find waiver of the *Electronic Devices* (724) argument (*i.e.*, that there is no direct infringement at the time of importation) and we find no abuse of discretion in his finding. See ID at 619 (finding elements not met). Furthermore, while Align argues prejudice, there is no reason why Align could not have asserted indirect infringement of the Group III claims in the complaint and before the ALJ, which Align failed to do.

Therefore, we affirm the ALJ's finding of no direct infringement of the Group III claims.

b. Contributory Infringement

The ALJ did not address the issue of contributory infringement of the Group III claims. *See* ID at 616-19; Align Pet. at 11.

Align acknowledges that it did not argue contributory infringement before the ALJ. In its petition for review, Align raises contributory infringement for the first time and asks to be excused from waiver: Align argues that "Respondents' failure to timely raise the 'computer-readable storage media' argument prejudiced Align; if Align had known that Respondents disputed the 'computer readable storage media' limitation,

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Align would have developed and asserted a contributory infringement theory.” Align Pet. at 11.

Respondents counter that Align never alleged contributory infringement and thereby waived the argument. Resp. Resp. at 4. Respondents argue that even if Align did not waive the argument, “the ALJ’s findings on induced infringement are fatal to any finding of contributory infringement.” *Id.* at 5.⁵⁴

Align had full opportunity to assert indirect infringement of the Group III claims in the complaint and before the ALJ. The Commission has not in the past allowed parties to assert new theories of infringement after the taking of evidence, when the ALJ has certified the record and rendered a final initial determination on violation. *See* 19 C.F.R. § 210.14(c) (amendment of pleadings may be granted when theory asserted during the taking of evidence). Even in the 724 investigation when the Commission found that there was no importation of an article that directly infringes, the Commission did not allow the parties to assert new theories of indirect infringement. *Certain Electronic Devices With Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Pub. 4374 (February 2013). The Commission has therefore determined to consider Align’s new theory of indirect infringement of the Group III claims to be waived.

⁵⁴ The ALJ found that there was no induced infringement with respect to claims 1 and 3 of the ‘880 patent because Align failed to show that CCPK possessed the requirement intent. ID at 589. Claim 1 of the ‘880 patent is in Group I and claim 3 of the ‘880 patent is in Groups I and IV. Respondents argue elsewhere that there is the same intent requirement for contributory infringement as for induced infringement, an argument we reject. Resp. Pet. at 56 (“The intent required to show contributory infringement is at least as high, if not higher, than the standard for induced infringement.”) (citing *Global-Tech Appliances v. SEB SA*, 131 S. Ct. 2060, 2067-68 (2011)). Align did not petition for review with respect to inducement, nor did it raise the issue in either of its briefs on review.

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4. Group IV Claims (Claims 1- 3, 11, 13-14, 21, 30-35, 38-39 of the '325 patent; Claims 1 and 3 of the '880 patent; Claim 1 of the '511 patent; and Claims 1, 2, 38-39, 41, and 62 of the '874 patent)

The Group IV claims are directed to methods of producing dental appliances starting with the images of the patient's teeth which are exported to Pakistan, manipulated abroad, and then imported. The final digital data sets are imported and the dental appliances are constructed by CCUS in the United States after importation.

a. Direct Infringement (Combining Foreign and Domestic Conduct and the Applicability of Section 271(g))

i. The ID

The ALJ found that CCPK and CCUS act in concert to practice the Group IV claims (although the ALJ found that claims 21 and 30 of the '325 patent and claim 1 of the '880 patent are also practiced independently by CCUS and claims 31 and 32 of the '325 patent are also practiced independently by CCPK).⁵⁵

As to the '325 patent, the ALJ found that CCPK and CCUS jointly practice every limitation of claims 1, 11, 21, 30, 33, 34, 35, and 38. ID at 477, 490-91, 503, 505, 517, 518, 523, 529.⁵⁶ As noted above, the ALJ found that CCUS also independently practices

⁵⁵ Claims 21 and 30 of the '325 patent and claim 1 of the '880 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group I if practiced independently by CCUS. Similarly, claims 31 and 32 of the '325 patent fall in Group IV if practiced by CCUS and CCPK together and fall in Group II if practiced independently by CCPK.

⁵⁶ The ALJ stated that CCUS practices dependent claim 2, ID at 478, but since he found that claim 1, from which claim 2 depends, was practiced by the concerted efforts of CCUS and CCPK, it appears that he meant to state that CCUS practices the additional limitation of claim 2 and that CCUS and CCPK together practice claim 2. Similarly, the ALJ found that CCUS practices dependent claim 39, where the practice should be joint. ID at 530. The ALJ appears to have made an analogous misstatement for certain claims with respect to CCPK, finding that CCPK practices dependent claim 3. ID at 484. It appears that he meant to state that CCPK practices the additional limitation of claim 3 but that CCUS and CCPK together practice claim 3. Similarly, the ALJ found that claim 13 is "substantively identical" to claim 3, ID at 492, and that CCPK practices claim 14, 31, 32. ID at 496, 513, 515. It appears that he meant to state that claim 31 is also jointly practiced and that claims 14 and 32 are jointly practiced based on the practice of the independent claims.

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claims 21 and 30 of the '325 patent. ID at 502-03, 504-05. As to the '880 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1 and 3. ID at 571-72, 577. The ALJ found that CCUS also independently practices claim 1 of the '880 patent. ID at 571. As to the '511 patent, the ALJ found that CCPK and CCUS practice every limitation of claim 1. ID at 638. As to the '874 patent, the ALJ found that CCPK and CCUS practice every limitation of claims 1, 2, 38, 39, 41, and 62. ID at 747, 748, 750-01, 753, 755-56, 758. The ALJ found that CCUS also independently practices claim 62 of the '874 patent. ID at 758.⁵⁷

With respect to the Group IV claims, the ALJ found a violation under 19 U.S.C. § 1337(a)(1)(B)(ii), *see* ID at 550-51, 592-93, 639, 758-59. He also found a violation under 35 U.S.C. § 271(g), apparently holding that infringement under 35 U.S.C. § 271(g) can serve as a predicate for a violation under 19 U.S.C. § 1337(a)(1)(B)(i), notwithstanding *Kinik v. ITC*, 362 F.3d 1359, 1363 (Fed. Cir. 2004) (defenses of § 271(g) do not apply to Section 337(a)(1)(B)(ii)). *See* ID at 432. For those claims which were jointly infringed (by CCPK's acts abroad and CCUS's acts in the United States), the ALJ held that foreign and domestic conduct may be combined by using 35 U.S.C. § 271(g) as a basis for direct infringement (with some claimed method steps performed prior to importation) and that this direct infringement could serve as a predicate for contributory infringement.

The ALJ suggested that infringement under section 271 of the Patent Act is limited to acts within the United States but that Section 337 is different because "[t]he purpose of section 337 from its inception was to provide relief to United States industry

⁵⁷ The ALJ found that CCPK practices the additional elements of dependent claims 2, 28, 39, and 41. Thus, by implication, CCUS and CCPK jointly practice these claims because they jointly practice claim 1 from which they depend.

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from unfair acts, including infringement of United States patents by goods manufactured abroad.” ID at 429-430 (citing *Lannom Mfg. Co., Inc. v. U.S.I.T.C.*, 799 F.2d 1572, 1580 (Fed. Cir. 1986)). The ALJ stated that: “The Commission made clear, however, that a violation of section 337 does not depend upon a violation of section 271, ...” *Id.* at 430 (citing *Certain Hardware Logic Emulation Systems*, Inv. No. 337-TA-383, Comm’n Op. (March 1998)). The ALJ rejected the IA’s argument that infringement must occur pursuant to 35 U.S.C. § 271(a) and cannot be premised on 35 U.S.C. § 271(g). *Id.* The ALJ found that “*NTP v. RIM* is not controlling on this point.” *Id.* The ALJ stated that “I reaffirm my finding that the parties’ arguments regarding the territorial limitations found in *NTP v. RIM* to apply to 35 U.S.C. § 271 are irrelevant to whether or not Respondents violate 19 U.S.C. § 1337(a)(1)(B)(i) or (ii).” *Id.* at 431.

The ALJ found that there is no requirement that the direct infringement occur prior to importation, and articles that contributorily infringe prior to importation may be the subject of Commission remedial orders. *Id.* The ALJ stated that “infringe” also includes 35 U.S.C. § 271(g). ID at 432-34. The ALJ held that while the defenses of 35 U.S.C. § 271(g) do not apply to investigations under Section 337(a)(1)(B)(ii), 35 U.S.C. § 271(g) may still as a basis for violation under Section 337(a)(1)(B)(i). ID at 434.

ii. Parties’ Arguments

The Respondents argue that the ALJ improperly combined foreign and domestic conduct to find infringement of method claims. Resp. Pet. at 11.⁵⁸ The Respondents

⁵⁸ The Respondents argue (in a footnote) that it does not appear that the ALJ relied on 271(g) to find infringement, and that 271(g) cannot be a basis for a finding of infringement under Section 337. Resp. Pet. at 10 n.1 (citing *Kinik Co. v. Int’l Trade Comm’n*, 362 F.3d 1359 (Fed. Cir. 2004) (holding that the defenses under §271(g) do not apply in Section 337 proceedings)). However, the ALJ held that § 271(g) was a basis for a finding of infringement (which Align argues allows the ALJ to combine foreign and

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quote the Federal Circuit in *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005):

We therefore hold that a process cannot be used ‘within’ the United States as required by section 271(a) unless each of the steps is performed within this country.

Id. Respondents further quote *Research in Motion* that, “if a private party practiced even one step of a patented process outside the United States, it avoided infringement liability . . .” *Id.* (citing *Zoltek Corp. v. United States*, 51 Fed. Cl. 829, 836 (2002)). Respondents therefore conclude that there can be no infringement under § 271(a) if *any part* of a step is performed outside of the U.S. *Id.*

Respondents state that there would be no infringement finding absent the ALJ’s errors of law. *Id.* (citing ID at 477, 491, 503, 505, 518, 527, 571, 577 and 747). The Respondents argue that even in the limited instances in which the ALJ found that one Respondent practiced all claim limitations, he still relied on combined conduct to find infringement. For example, Respondents acknowledge that the ALJ found that CCUS performed all of the limitations of two independent claims—claim 21 of the ‘325 patent and claim 1 of the ‘880 patent—but argue that the ALJ expressly noted that CCUS and CCPK “act in concert to practice claim 21 of the ‘325 patent.” *Id.* (discussing ID at 503; 566-71).

domestic conduct), ID at 434. Respondents may be basing their statement on the fact that the ALJ also held that contributory infringement may occur through the combination of foreign and domestic conduct. See ID at 434 and n.31. The Respondents further assert that, if 271(g) did apply in Section 337 investigations, it would not apply in a case of “divided infringement” where part of the process is performed in the United States. *Id.* (citing *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, 813 F.Supp.2d 602, 613-14 (D. Del. 2011)).

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Conversely, the Respondents acknowledge that the ALJ found that CCPK itself practices each claim limitation of claim 31 of the ‘325 patent, claim 1 of the ‘863 patent, claim 1 of the 487 patent, and claims 1 and 7 of the ‘666 patent, but argue that the ALJ improperly combined CCPK’s conduct with that of CCUS. Respondents state that throughout his ID, the ALJ consistently found that CCUS performed the step of providing data sets when it sent the initial data sets to CCPK or otherwise provided the initial scan to it, discussing ID at 475, 498-90, 530, but the Respondents assert that Align argued that when the data set is received in both the United States and Pakistan, Align alleges a joint process that does not occur entirely within Pakistan or the United States.

The Respondents argue that the ALJ erred when he impermissibly combined the Respondents’ independent conduct to find “concerted” infringement. The Respondents refer to *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (*en banc*), and argue that liability for induced infringement requires direct infringement by a single actor.

The Respondents state that the ALJ combined the Respondents’ acts to find direct infringement, citing the Respondents’ “concerted efforts” or acts “in concert” as support for his infringement conclusions. *See* Resp. Pet. at 9 (referring to ID at 477, 491, 503, 571, and 747 for “concerted efforts” findings and ID at 505, 518, 522, 527 and 577 for “in concert” findings. The Respondents further argue that the ALJ accepted and approved the testimony of Align’s lone infringement expert, Andrew Beers, who likewise relied on combined acts to opine about infringement. *Id.* (citing Tr. 541:14 to 555:9 for his testimony about the independent claims of the ‘325, ‘880, ‘487, ‘863 and ‘666 patents and 583:21 to 586:13 for his testimony about the ‘511 and ‘874 patents; ID at 434-35).

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Align argues that the ALJ did not “improperly combine foreign and domestic conduct” to find infringement. Align notes that Respondents cite *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) for the proposition that, to find infringement of a process claim under 35 U.S.C. § 271(a), all of the claimed steps must be performed in the United States. Align Resp. to Resps. at 7. However, Align counters that this proposition does not apply to other parts of 35 U.S.C. § 271 such as § 271(g). *Id.* at 8.

Align states that the ITC has instructed that “infringe” includes “all forms of infringement,” which would include § 271(g) claims. *Id.* (citing *Certain GPS Chips, Assoc. Software and Sys. and Prods. Containing Same*, Inv. No. 337-TA-596, 2010 ITC LEXIS 582, at *81 (Mar. 2010)). Align argues that while it is true that the court has found that the defenses of § 271(g) do not apply in the context of a violation under 337(a)(1)(B)(ii), this finding is inapplicable to Align’s present assertions. *Id.* (discussing ID at 432–34). Align argues that both 35 U.S.C. § 271(a) and 35 U.S.C. § 271(g) infringement is “direct infringement” for purposes of Section 337(a)(1)(B)(i). Align Resp. to IA at 5-6. Align states the Federal Circuit has repeatedly confirmed that infringement under 35 U.S.C. 271(g) is a form of direct infringement. *Id.* at 5. Align cites district court precedent for the proposition that infringement under § 271(g) may serve as a basis for indirect infringement under 271(b) or (c). *Id.*

Align argues that the IA has conceded that the holding of *Kinik* is limited to the [non]application of the § 271(g) defenses to Title 19. Align Resps. to IA Pet. at 9.

Align further argues that the Federal Circuit recently confirmed in *Akamai* that the process steps of the asserted claims do not have to be performed by a single entity for §

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271(g) infringement. *Id.* (citing *Akamai*, 692 F.3d at 1306). Align asserts that no one advances a theory involving multi-actor performance of method steps under 35 U.S.C. § 271(a). *Id.* at 4.

With respect to the Group IV claims, Align argues that Respondents violate 337(a)(1)(B)(i) when they import, sell for importation, or sell after importation, digital data sets made by CCPK according to the steps of various claims, and CCUS then creates aligners based on the digital data. *Id.* at 5. Align argues that these are the imported digital data sets that contributorily infringe under 35 U.S.C. § 271(c), and the ultimate sale, offer for sale, or use of the manufactured aligners by CCUS is a direct infringement under 35 U.S.C. § 271(g). *Id.* at 5-6. Align argues that Respondents' arguments are again irrelevant, as the asserted basis is § 271(g), not § 271(a).⁵⁹ *Id.*

The IA argues against the ALJ's legal conclusion that claims under 35 U.S.C. § 271(g) are cognizable as direct infringement before the Commission, and any infringement determinations based thereon. The IA notes that in *Kinik*, the Federal Circuit "affirm[ed] the Commission's ruling that the defenses established in § 271(g) are not available in § 1337(a)(1)(B)(ii) actions." 362 F.3d at 1363. The IA submits that *Kinik*'s holding regarding section 271(g)'s defenses indicates that section 271(g) infringement claims are also not cognizable as direct infringement before the Commission. Furthermore, the IA argues that Congress enacted 35 U.S.C. § 271(g)'s process patent provisions at the same time, and within the same act, in which it incorporated the Commission's separate process patent authority into 19 U.S.C. 1337(a)(1)(B)(ii), and argues that had Congress intended to incorporate the process patent

⁵⁹ See also Align's Response to Staff's Petition, Issues A and B.

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standards of 35 U.S.C. § 271(g) into the Commission's authority regarding process patents, it could have done so explicitly. *Id.* (citing *See Abrasive Products*, Inv. 337-TA-449, Comm'n Op. Affirming ALJ Order No. 40 at 3); *Amgen, Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 851 (Fed. Cir. 2009) ("In *Kinik* . . . this court explained that § 271(g) provided a new right and remedy in the district court, but held that the Tariff Remedy of exclusion based on practice of a patented process was unchanged."). The IA states that OUII is not aware of any post-*Kinik* Commission opinions that have adopted an infringement theory based on § 271(g). The IA states that in *Certain Rubber Antidegradants, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-533, the ALJ's Final ID discussed the legal standards for infringement, referring in passing to §§ 271(a) and 271(g), ID at 93–94 (Feb. 17, 2006), but the Commission re-characterized the infringement determination as one that should be assessed pursuant to Section 337(a)(1)(B)(ii). *Rubber Antidegradants*, Inv. 337-TA-533, Comm'n Op. at 2, 9 n.2 (Jul. 24, 2006), vacated on other grounds, 511 F.3d 1132 (Fed. Cir. 2007).⁶⁰

The IA states that CCUS and CCPK are not independent entities, because, according to the IA, the overwhelming evidence does not support ClearCorrect's contention. IA Resp. at 16. Nevertheless, the IA agrees with the Respondents that the ALJ erred in his finding to the extent that the ID combined foreign and domestic conduct to find infringement of method claims under either 35 U.S.C. § 271(a) or § 271(g). IA Resp. at 16 n.3 (citing IA Pet. 4–10).

⁶⁰ The IA notes that, according to the Complainant, infringement of the following claims was based on 35 U.S.C. § 271(g): claims 1, 2, 3, 11, 13, 14, 30, 33, 34, 35, 38, and 39 of U.S. Patent No. 6,217,325; claim 3 of U.S. Patent No. 6,722,880; claim 1 of U.S. Patent No. 6,471,511; and claims 1, 2, 38, 39, 41, and 62 of U.S. Patent No. 7,134,874.

PUBLIC VERSION**iii. Analysis**

The ALJ found a violation with respect to the Group IV claims under Section 337(a)(1)(B)(ii) and Align argues that the ALJ also found violation under 35 U.S.C. § 271(g). The pertinent questions are whether there is violation under Section 337(a)(1)(B)(ii), whether 35 U.S.C. § 271(g) is applicable to Section 337 as an alternative theory propounded by Align, and if so, whether § 271(g) would cover the Group IV claims.

First, we find that the ALJ erred in finding a violation of Section 337(a)(1)(B)(ii) with respect to the Group IV claims because the imported digital data sets are not the end product of the Group IV claims, which disclose methods for fabricating dental appliances. Therefore, because the Group IV claims are directed to fabricating dental appliances, the last claim step is not performed prior to importation as required by Section 337(a)(1)(B)(ii).

Second, we find that Align is mistaken when it argues that infringement under 35 U.S.C. § 271(g) can form the basis for a finding of violation of Section 337(a)(1)(B)(i). Align argues that 35 U.S.C. § 271(g) is included in the term “infringe” in Section 337(a)(1)(B)(i). It is a well-established canon of statutory construction that a specific provision governs over a general provision. *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. —, —, 132 S. Ct. 2065, 2068 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, 112 S. Ct. 2031, 119 L.Ed.2d 157 (1992)). The existence of Section 337(a)(1)(B)(ii), which specifically defines violations of Section 337 based on the importation of articles produced by a patented process, persuades us that violations of Section 337 based on process of manufacture

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claims should not be addressed under Section 337(a)(1)(B)(i) read in conjunction with § 271(g). Section 337(a)(1)(B)(ii) is a special provision which governs over the general provision of Section 337(a)(1)(B)(i). Therefore, violation premised on the importation (or sale after importation) of articles produced by a patented process should be analyzed under Section 337(a)(1)(B)(ii) rather than Section 337(a)(1)(B)(i). *See id.*

The Court in *Kinik Co. v. ITC*, explained that the Process Patent Amendments which created Section 271(g) were not intended to change existing remedies at the Commission. 362 F.3d 1359, 1362-63 (Fed. Cir. 2004) (holding that the statutory defenses to infringement under 35 U.S.C. 271(g) were not available as defenses to Section 337(a)(1)(B)(ii) at the Commission) (“However, § 9006(c) of the Process Patent Amendments Act, *supra*, states the intent to preserve all existing remedies, as elaborated in the Senate Report.”) Indeed, the Federal Circuit in *Kinik* stated that “It was explained [in the legislative history] that § 271(g) was intended to provide ‘patent owners the new right to sue for damages and seek an injunction in Federal district court.’” 362 F.3d 1359, 1362 (Fed. Cir. 2004) (quoting S. Rep. No. 100-83 at 27 (1987)). Thus, § 271(g) was intended to serve as a supplement in district courts analogous to the practice at the Commission, and the re-enactment of Section 337a as Section 337(a)(1)(B)(ii) was intended to govern practice at the Commission regarding process patents. Further, the Court in *Kinik* did not apply the defenses of § 271(g) to Section 337(a)(1)(B)(ii). If § 271(g) applied, then the defenses would apply. They do not.

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Because § 271(g) does not apply to Section 337, we need not address the indirect infringement allegations regarding Group IV claims.⁶¹ In conclusion, we find no violation with respect to the Group IV claims.

D. Invalidity

The only claims which the Respondents specifically cite for anticipation and obviousness, as exemplary claims to represent the entire ID, are claims 1, 37, and 38 of the '325 patent. Resps. Pet. at 48 n.80 ("The ALJ made this finding throughout the *ID*. For example, he applied this finding in claims 1, 37, & 38 of the '325 Patent.").⁶² Since Respondents failed to make a specific case for any of the other claims, the Commission has determined that they have waived any similar arguments with respect to those claims.⁶³

⁶¹ Parenthetically, we note that even if § 271(g) applied to the Commission, it is our view that § 271(g) only applies to imported products made abroad by patented processes. We have not been briefed with any case, and we have not found any case, in which the Federal Circuit has applied § 271(g) to conduct that is entirely domestic (*i.e.*, with no importation).

⁶² Claim 37 of the '325 patent was not asserted in this investigation.

⁶³ Although the Respondents do not make separate arguments for each of the asserted claims, the Respondents appear to argue that each of the 40 asserted claims is anticipated or obvious, and adopt, for the purposes of their invalidity analysis, a uniform characterization of the asserted claims as involving a five-step process for making aligners: (1) a digital representation of the patient's existing teeth arrangement is created; (2) the representation is digitally modified to allow each individual tooth to be manipulated; (3) 3D graphics software is used to move the virtual teeth to the desired (final) position; (4) virtual intermediate tooth arrangements are created (by interpolation between the initial and final positions); and (5) physical molds are created to form aligners. Resps. Pet. at 39. We note that some of the claims are directed to digital data sets, but the Respondents argue invalidity in generic terms (*i.e.*, not differentiating the asserted claims), arguing with respect to what they characterize as the patentee's method (above) for manufacturing dental appliances.

PUBLIC VERSION**1. Prior art at issue****a. U.S. Patent No. RE35,169 (“Lemchen”)**

Lemchen, entitled “Method for Determining Orthodontic Bracket Placement,” discloses a method for determining orthodontic bracket placement on a maloccluded⁶⁴ tooth to correct the malocclusion by repositioning of the tooth to a “finish” position. Lemchen was originally filed on January 24, 1989, and is prior art to all patents-in-suit. Lemchen’s disclosed method includes the steps of: (1) generating digital information which defines the shape and location of the maloccluded tooth in the patient’s jaw, from which digital information a mathematical model of the tooth and jaw is generated; (2) calculating the “finish” position of the maloccluded tooth or teeth from the digitized information, with respect to their positions in the model; (3) calculating the correct placement of a bracket from the digitized information; (4) modifying the bracket in view of the patient’s physical deviations from the statistical averages; and (5) forming an archwire (force-producing attachment) for the brackets. Also, the method may be used on one or more teeth in the same dental arch, as well as for both dental arches with respect to malocclusion between them. CX-945 (Lemchen), Abstract, 2:48-4:16.

Further, the method may generate the digital information in a variety of ways, including electromechanically, using laser scanning, sonic ranging, digital video scanning, or magnetically. *Id.* The method may also use computer-aided design (“CAD”) techniques to generate the mathematical model, and the repositioning may be done mathematically by appropriate software programs which may be derived by conventional means for the particular method of treatment elected by the orthodontist.

⁶⁴ Malocclusion is faulty contact between upper and lower teeth when the jaw is closed.

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Id. Also, Lemchen specifically refers to Figs. 1 and 3 of U.S. Patent No. 2,467,432 (“Kesling”) as prior art examples, respectively, of a physical embodiment of the mathematical model and a manual step of physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. *Id.* at 3:7-15, 25-40.

b. U.S. Patent No. 2,467,432 (“Kesling”)

Kesling, entitled “Method of Making Orthodontic Appliances and of Positioning Teeth,” discloses a method for providing removable tooth positioning appliances (*i.e.*, aligners) which are adapted to be used to maintain or bring the teeth of the user into a predetermined ideal or desirable position without the necessity for the use of metallic bands, wires, or any other prior art appliance. Kesling was originally filed July 23, 1943, and is prior art to all patents-in-suit. The disclosed method includes the steps of: (1) generating a physical model, *e.g.*, a cast, of the teeth to be repositioned; (2) removing the teeth to be repositioned from the model; (3) resetting the teeth in their desired positions; (4) generating a new model of the repositioned teeth; and (5) using the new model, generating a tray for taking an impression of the repositioned teeth which is used to form the removable tooth positioning appliance to be worn by the user. CX-944 (Kesling), 1:1-8, 2:43-4:70. Fig. 1 of Kesling illustrates a plaster model of an upper and lower jaw and shows the condition of the patient’s teeth prior to the beginning of treatment. *Id.* at Fig. 1, 2:7-9. Fig. 3 illustrates a similar plaster cast and shows the teeth after they have been dissected from the cast, and reset upon the same base to show the ideal position in which they are finally to be positioned. *Id.* at Fig. 3, 2:15-21.

PUBLIC VERSION**c. U.S. Patent No. 6,471,511 ("the '511 patent")**

The '511 patent, entitled "Defining Tooth-Moving Appliances Computationally," is asserted by Align in this investigation and discloses a method and corresponding apparatus for segmenting an orthodontic treatment path, *i.e.*, repositioning of trouble teeth to a "finish" position, into clinically appropriate substeps to perform correct repositioning using tooth-moving appliances. The '511 patent was originally filed June 20, 1997. The disclosed method includes the steps of: (1) acquiring a mold of the patient's teeth and tissue using a variety of methods including direct contact scanning and imaging that provides information about the structure of the teeth, jaw, gums, and other orthodontically relevant tissue; (2) deriving a digital data set from the mold and the orthodontic information that represents the initial arrangement of the patient's teeth and other tissues; (3) processing the digital data set to segment extraneous elements, *e.g.*, individual tooth crowns, hidden surfaces, and root structures, from each other; (4) calculating the desired final position of the teeth, *i.e.*, the end result of orthodontic treatment, using a clinical prescription such that the final position and surface geometry of each tooth can be specified; (5) using the beginning and finish teeth positions, defining a tooth path for the motion of each tooth which is optimized so that the teeth are moved in the quickest fashion with the least amount of duplicative back-and-forth tooth movement to bring the teeth to their desired final positions; (6) segmenting the tooth paths so that each tooth's position within a segment stays within threshold limits of linear and rotational translation; and (7) using the segmented tooth paths and associated tooth position data to calculate and make clinically acceptable appliance configurations (or successive changes in appliance configuration) that will move the teeth on the defined

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treatment path in steps specified by the path segments. Also, the method discloses that the appliances can be braces, polymeric shells, or other forms of orthodontic appliance. JX-1 (“the ‘511 patent”), Abstract, Fig. 1, 3:22-4:67.

2. Anticipation

Respondents contend that Lemchen incorporates Kesling and anticipates the asserted claims of the ‘325 patent.

a. Relevant Law

A patent is presumed valid, and a party challenging validity has the burden of proving invalidity by clear and convincing evidence. *See 35 U.S.C. § 282; Iron Grip Barbell Co., v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004). A patent claim is invalid as anticipated if “the invention was known or used by others, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, [.]” 35 U.S.C. § 102(a). Anticipation requires that a single prior art reference discloses each and every limitation of the claimed invention. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003). The Federal Circuit has held that “[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document.” *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (*citing Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997)).

b. Does Lemchen Incorporate Kesling In Whole or In Part?

A threshold issue is whether Kesling is fully incorporated by reference into

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Lemchen.⁶⁵ At the hearing, respondents contended that asserted claims 1-3, 11, 13-14, 21, 30-35, and 38-39 of the '325 patent, where claim 1 is representative, are anticipated by Lemchen, which they purported fully incorporates Kesling by reference. ID at 108, 148-68. The two passages in Lemchen incorporating Kesling read:

Thus, in many applications of the preferred embodiment, a complete “model”, as that term is used in the dental art to refer to a full replication of the upper and lower dental arches and associated jaw structure, will be mathematically generated. A physical embodiment of such a model is shown, for example, in FIG. 1 of [Kesling].

Id. at 145 (citing Lemchen, 3:10-15).

In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model in the finish position. See, for example, FIG. 3 in the above referenced [Kesling].

Id. (citing Lemchen, 3:35-40).

However, the IA and Align argued that Kesling was not fully incorporated by reference into Lemchen by these passages. *Id.* at 128-38, 139-42.

Reviewing the relevant precedent, the ALJ found that “[t]o incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.” ID at 142 (citing *Advanced Display*, 212 F.3d at 1282 (citing *In Re Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973))). The ALJ noted, however, that the Federal Circuit and its predecessor have limited incorporation to the portions of the external reference that are specifically identified in the incorporation language of the host

⁶⁵ Also at issue is whether the ALJ properly limited the evidentiary use of certain expert reports from the *Ormco* litigation. *See infra.*

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document. *Id.* at 143-44 (citing *Zenon Environmental, Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1379 (Fed. Cir. 2007); *In re Saunders*, 444 F.2d 599, 600 (C.C.P.A. 1971).

Applying the relevant case law, the ALJ found that the incorporation language of Lemchen identifies with detailed particularity what specific material it incorporates from Kesling and clearly indicates where the material is found, *i.e.*, Figs. 1 and 3 of Kesling. *Id.* Accordingly, the ALJ concluded that Lemchen does not incorporate Kesling beyond Figs. 1 and 3 of Kesling. *Id.* Further, even assuming *arguendo* that Lemchen incorporates fully by reference Kesling, the ALJ still found no anticipation because each and every limitation of claim 1 of the '325 patent is not disclosed by Lemchen and Kesling. *Id.* at 146.

Respondents contend that the ALJ clearly erred on the threshold issue of whether Lemchen fully incorporates Kesling. Respondents' Pet. at 36-38. They argue that language in a patent such as “[r]eference is made to” can be sufficient to indicate to one of ordinary skill in the art that the referenced material is *fully incorporated* [into] the host document.” *Id.* at 36 (citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (emphasis added)). They argue that Lemchen uses similar language and makes clear that it is referring to the “methods of treatment” in the prior art, and not just the figures in stating: “In the prior art, a similar step was accomplished manually in order to account for individual tooth morphology by physically removing duplicated teeth from a model and repositioning them in a new model I the finish position.” *Id.* (citing Lemchen, 3:35-40). They further argue that it is important to consider the entirety of the incorporated document to properly understand its teachings, particularly because Kesling is small and only contains one page of figures and approximately 3.5 pages of text. *Id.* at

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38 (citing *In re Hughes*, 550 F.2d 1273, 1275-76 (C.C.P.A. 1977)). They submit that Figs. 1 and 3 of Kesling are substantively discussed repeatedly throughout the first two pages of the reference, and are essentially omitted only from the claim section and the listing of the prior art. *Id.*

Align points out that Lemchen only briefly refers to two *figures* from Kesling. Align's Resp. at 21 (emphasis added). Align argues that these references to Figs. 1 and 3 of Kesling are used only as examples of *models*, and that Lemchen does not state that the *entire* disclosure of Kesling or any of its *particular* methods are incorporated. *Id.* (emphasis added). Complainant submits that Lemchen's use of the language "in the above referenced [Kesling]" is merely citing Lemchen's prior reference to Fig. 1 of Kesling. *Id.* Align also contends that Lemchen's use of the language "methods of treatment" merely refers to different methods of treating a patient with brackets and archwires – not the removable appliance disclosed by Kesling. *Id.* (emphasis added).

The Commission has determined to affirm the ALJ's finding that Lemchen does not incorporate Kesling in its entirety, as set forth in the ID at 142-48. Incorporation by reference requires the host document to "identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents." *See Advanced Display Sys.*, 212 F.3d at 1282. Lemchen specifically discloses that the "physical embodiment of such a [digital] model is shown, for example, in FIG. 1 of [Kesling]." This passage thus refers to a model of a patient's jaw structure in Kesling that is found solely in Fig. 1 of Kesling, thereby obviating any need to view other portions of Kesling to understand the incorporated subject matter. Further, Lemchen specifically discloses that this physical model is shown, "for example, [in] FIG. 3 in the

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above-referenced [Kesling].” *Id.* at 3:39-40. Again, based on this specific language of Lemchen, this refers to a model of a patient’s jaw structure, this time with the teeth repositioned in the finish position, that is found solely in Fig. 3 of Kesling.

The patents in the precedent cited by Respondents used different language than the patent here which clearly indicates what subject matter is incorporated and where it can be found. In both *Callaway Golf* and *Hughes*, the material to be incorporated was designated more broadly. *See Callaway Golf*, 576 F.3d at 1346; *Hughes*, 550 F.2d at 1275-76. Further, in *Mobile Devices* the incorporation by reference language was not in dispute. *See Certain Mobile Devices, Associated Software, and Components Thereof (“Mobile Devices”)*, Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011).

c. Comparison of Exemplary Claimed Process to Prior Art

The ALJ found that Lemchen describes “generating digital information” regarding the initial “maloccluded teeth,” and then determines their respective “finish positions.” ID at 146-47. The ALJ found that Lemchen discloses calculating positions on the teeth for bracket placement, and completes movement of the teeth with traditional brackets and archwires, not polymeric shell, *i.e.*, removable, appliances. *Id.* (citing CX-495 at 1-2, CX-1247C at Q. 186). However, he found that Align’s expert (Dr. Valley) credibly testified that Lemchen does not disclose, teach, or suggest calculating positions-in-between. *Id.* (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). As a result, the ALJ found that Lemchen does not disclose “producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement,” as required by exemplary claim 1 of

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the '325 patent. *Id.* Based on the foregoing, the ALJ found that Lemchen does not disclose “fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets,” as required by claim 1 of the '325 patent. *Id.* at 147.

The ALJ further found that the incorporation of Figs. 1 and 3 of Kesling, as well as its full incorporation, into Lemchen does not disclose these limitations of claim 1. *Id.* He noted that Kesling was originally filed in 1943 and issued in 1949, before the concept of digital data existed. *Id.* Also, he found that Dr. Valley testified credibly that Kesling “does not disclose, teach, or suggest, or even remotely contemplate” the use of computers or digital technology. *Id.* (citing CX-1247C at QQ. 141-42, 564-71, 574-77). He also found that Kesling describes making tooth arrangements by (1) using a plaster mold of teeth, (2) separating the plaster teeth with a saw, and (3) reassembling the plaster teeth in wax into their assumed positions. *Id.* at 148 (citing CX-944 at 3).

In addition, the ALJ found that Dr. Valley testified credibly that Kesling only contemplated a reactive process, performed one step at a time, where appliances beyond a first appliance may be created by repeating the disclosed process for making the first appliance. *Id.* (citing CX-1247C at QQ. 144-45, CX-944 at 5). He further found that Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.* Rather, he found that Kesling discloses manually making an appliance using tools, supplies, and materials, including by, *inter alia*, (1) articulating the plaster cast; (2) taking an impression of the teeth of the plaster

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cast; and (3) making a mold filled with the appliance material. *Id.* (citing CX-944 at 3-4, CX-1247C at Q. 146).⁶⁶

Based on the foregoing, the ALJ concluded that respondents failed to meet their burden to prove by clear and convincing evidence that Lemchen anticipates independent claims 1, 11, 21, 31, 33, 35, and 38 of the '325 patent. *Id.* at 148. Based on his non-anticipation finding with respect to these asserted independent claims, he also found that asserted dependent claims 2-3, 13-14, 30, 32-34, and 39 are not anticipated by Lemchen. *Id.* at 148-171.

The Respondents argue that, once it is correctly found that Lemchen fully incorporates Kesling by reference as respondents argue, Lemchen anticipates the asserted claims of the '325 patent. Resps. Pet. at 39-48. Specifically, Respondents submit that Kesling teaches the following: (1) creating a model of the teeth in their existing position (citing Kesling, 2:7-9); (2) methods for modifying the initial model to allow the teeth to be individually manipulated (citing Kesling, 3:30-49); (3) methods for moving the modeled teeth to the desired location (citing Kesling, 3:49-64); (4) creating intermediate tooth arrangement models between the existing tooth arrangement model and the desired arrangement (citing Kesling, 2:50-3:1); and (5) a plurality of successive or intermediate

⁶⁶ The ALJ observed that, in previous litigation, the Federal Circuit found that the asserted claims of certain Align patents describing systems and methods for incrementally repositioning teeth, U.S. Patent Nos. 6,554,611 ("the '611 patent") and 6,398,548 ("the '548 patent"), are rendered invalid in view of prior art showing use of such systems and methods by orthodontists. *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1302 (Fed. Cir. 2006). Respondents asserted *Ormco*'s findings, especially Dr. Diane Rekow's (expert for Align in the litigation) expert reports from that litigation from Dr. Diane Rekow (Align's expert in that litigation), as proof of the knowledge of one of ordinary skill in the art and invalidity of the patents at issue here. *Id.* at 187 (also at 201, 219-20, 380, 397). However, the ALJ ruled that respondents' evidentiary exhibits (RX-102C and RX-103C) that contained the expert reports from *Ormco*, which included reports on the issue of the asserted combination of Lemchen and Kesling, were limited in evidentiary use to show only that Align took an inconsistent position in *Ormco*. *Id.* at 187 (also at 201, 219-20, 380, 397); *see also* Tr. at 20-21 (granting-in-part Align's motion in limine to exclude the reports as hearsay).

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tooth positions and the fabrication of a series of appliances based on the intermediate tooth positions as recited by claim 1 of the '325 patent.

Align submits that the ALJ correctly concluded that, even assuming *arguendo* that Lemchen fully incorporates Kesling, this combination does not render any of the asserted claims obvious because it still does not disclose all elements of the claims. Align Resp. to Resps. at 23-29. Align submits that, contrary to respondents' contention, the claimed feature of determining intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement is completely absent from Kesling and Lemchen. *Id.* at 24-25 (citing CX-1247C at QQ. 137-62; CX-1254C, ¶ 62-65 at 21-23, ¶ 67 at 24-25, Tr. at 790-93). Specifically, Align contends that Kesling does not disclose, *inter alia*, the following claimed features: (1) digital data sets or models of a dentition; (2) intermediate or successive tooth arrangements based on initial and final positions; (3) fabricating a dental appliance, or controlling a fabricating machine, based on a digital data set; or (4) numerous other elements. *Id.* at 25. Rather, Align contends, Kesling only discloses a *reactive* process, done *one step at a time*, where subsequent appliances are created by repeating the process for making the first. *Id.* at 24 (emphasis added).

The Commission affirms the ALJ's finding and adopts the ALJ's reasoning, as set forth in the ID at 142-48 and 168-69, that Lemchen does not anticipate claim 1 or 38 of the '325 patent.⁶⁷ Lemchen does not teach interpolation or how to create successive appliances. ID at 149 (citing CX-945 at 1-3, CX-1247C at QQ. 184-85). Further, we

⁶⁷ Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated by Lemchen, whether or not it incorporates Kesling.

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agree with Align that Lemchen does not discuss defining or moving tooth boundaries.

We agree with the ALJ that this combination, even assuming *arguendo* that Kesling is fully incorporated into Lemchen, still fails to disclose the claimed feature of mathematical interpolation.

3. Obviousness

a. Relevant Law

Under 35 U.S.C. § 103(a), a patent is valid unless “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” See 35 U.S.C. § 103(a). Once claims have been properly construed, “[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of non-obviousness” (also known as “objective evidence”). See *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1354 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

The Supreme Court rejected a “rigid approach” to prove obviousness, that requires an express “teaching, suggestion, or motivation to combine references,” in favor of a non-formalistic approach that considers other factors, e.g., demands of the market and the technical community, interrelated teachings of multiple patents, background knowledge of one skilled in the art, inferences and creative steps one skilled in the art would employ, etc. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). All of these

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factors may be considered by the court to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *Id.* at 417-21.

b. Combination of Lemchen and Kesling for all Asserted Claims

The ALJ found that Lemchen combined with Kesling would not render obvious any asserted claim of the '325 patent. ID at 181-223. Focusing on the motivation to combine references, the ALJ found that the mention of Kesling in Lemchen would be adequate to cause a person of ordinary skill in the art to consider both references in combination. *Id.* at 182. However, the ALJ found that Kesling "does not disclose, or teach or suggest, or even remotely contemplate" the use of computers or digital technology, and Kesling does not expressly or inherently disclose, or teach or suggest, fabricating a dental appliance based on a digital data set. *Id.*

The Respondents submit that the only difference between Kesling and the claimed subject matter of the asserted patents is the use of digital data. Resps. Pet. at 41. They submit that the mere application of modern electronics to existing subject matter is commonplace and obvious to one skilled in the art. *Id.* (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); *Western Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1370 ("Our conclusion of obviousness was based in part on the reasoning that applying modern electronics to older mechanical devices has been commonplace in recent years.")); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) (the

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Court rejecting arguments that such incorporation, *i.e.*, applying modern electronics to a prior art mechanical device, would have been beyond the ability of a person of ordinary skill in the art)).

Respondents argue that the record in this investigation demonstrates that the asserted claims are for digitally performing operations, such as interpolation, which were previously performed in an analog manner and therefore are invalid as obvious. *Resps. Sub.* at 12. Respondents assert that the technology at issue is easy to understand, and that the fact that analog methods were performed to accomplish the same steps to make aligners cannot be meaningfully disputed. *Id.* at 12. Respondents point to the *Ormco* litigation in which the Federal Circuit held claims of other of Align's patents to be invalid, and argue that "[t]hese holdings, discussed in greater detail in Respondents' petition for review, conclusively demonstrate that analog and digital methods of designing and manufacturing aligners predated Align's asserted claims." *Id.* at 13 (citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1313-18 (Fed. Cir. 2007)).

Respondents discuss the Kesling analog system, *Id.* at 13-14, and cite the expert report from the *Ormco* litigation for the proposition that the only difference between Kesling and the claimed subject matter is the use of digital technology. *Id.* at 14 (RX-103C at 2). Respondents argue that Lemchen taught the use of 3D graphics to move the virtual teeth to the desired position. *Id.* at 15 (citing CX-945 at 2:66-3:6). Respondents argue that each individual step of the claimed methods was known and performed both manually and digitally prior to the claimed invention. *Id.* at 17-19 (citing RX-103C at 2).

Respondents argue that Dr. Rekow's expert report in the *Ormco* litigation and Dr. Mah's testimony set forth the motivation to combine. *Id.* (citing RX-103C at 2; RX-113 Q.95).

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Align asserts that its inventions are not simply computerized versions of prior art systems. Align Sub. at 14. Align states that Respondents never submitted any evidence that the asserted claims merely recite manual methods using modern electronics. *Id.* at 14-15. Align argues that one significant difference between Align's asserted claims and the prior art is Align's inventive concept of determining intermediate or successive states based on the initial and desired final states. *Id.* at 15. Align continues that Dr. Valley, Align's expert, explained why this is fundamentally different from the prior art. *Id.* at 16 (citing, CX-1247C at Q.141, 144-45, 183-85, 293-95, 304-06, 335-38, 410, 412, 414-15, 418-22, 440-41, 443-44; CX-1254C ¶¶ 65, 82, 126, 149-50, 194; Tr. at 791:21-793:5, 794:3-795:17).

Align argues that Kesling describes a reactive process, done one step at a time based on the position of the teeth, and repeated, and that Kesling's method is not based on the initial and final positions. *Id.* at 16 (citing ID at 147; CX-1247C at Q.144-45; CX-1254C at ¶ 65; Tr. at 790:9-791:20). Align argues that Respondents do not dispute this and that Dr. Rekow testified in the *Ormco* litigation only that Kesling moved the teeth by incremental amounts. *Id.* at 16-17 (citing RX-103C at 13).⁶⁸ Align asserts that the prior art fails to disclose other limitations of other claims either in digital or physical form, e.g., "interpolation," which is recited in claim 14 of the '325 patent, claim 8 of the '863 patent, and claims 3, 7, and 9 of the '666 patent.

Align contends that the authority relied on by Respondents is readily distinguishable. *Id.* at 18. Align argues that *Leapfrog Enters. v. Fisher-Price, Inc.*, 485

⁶⁸ Regarding the *Ormco* expert reports, Align submits that the ALJ was correct to limit respondents' use of these reports. Align Resp. to Pet. at 30-31. Align submits that only relevant, reliable, and material evidence is admissible in Commission proceedings. *Id.* (citing 19 C.F.R. § 210.37(b)).

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F.3d 1157 (Fed. Cir. 2007), is distinguishable because Align's invention is not merely an old system with new parts. Align argues that *Western Union Co. v. MoneyGram Payment Sys.*, 626 F.3d 1361 (Fed. Cir. 2010), is distinguishable because Align's inventions are not merely an upgrade to an old or existing system. Align argues that Respondents have no support (except citation to Dr. Rekow's report in the *Ormco* litigation) for their claim that Lemchen taught intermediate tooth arrangements and that applying digital technology to prior art was obvious to one of ordinary skill in the art. *Id.* at 8.

The IA argues that the testimony provided by Respondents' expert Dr. Mah is merely conclusory and does not make up for the deficiency with respect to the claimed knowledge of one of ordinary skill or the alleged motivation to apply any digital technology. IA Sub. at 8 (citing RX-113C at QQ.114-121).

The IA asserts that the use of digital data is not the only difference between Kesling's teachings and the subject matter of the asserted claims. *Id.* at 9. The IA states that the ALJ found that Kesling contemplated a reactive process, and that Lemchen does not disclose or teach calculating positions in between. *Id.* (citing ID at 146-47).

The Commission affirms the ALJ's findings, and adopts the ALJ's reasoning, as set forth in the ID at 180-82 and 203-206, that Respondents have not proven that claim 1 or claim 38 of the '325 patent is obvious.⁶⁹ Kesling and Lemchen do not teach the interpolation of digital data sets, and Respondents have not cited any substantive evidence of record to support the defense that the asserted claims are an obvious

⁶⁹ Further, although Respondents have not petitioned with specificity with respect to other claims, the Commission explicitly adopts the ALJ's findings in the ID that Respondents have not proven that the remaining claims of the patents in suit are anticipated or rendered obvious by Lemchen, whether or not it incorporates Kesling.

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application of digital technology. Respondents point only to the expert report of Dr. Rekow, Align's expert, from the *Ormco* litigation, which the ALJ held could only be used for impeachment purposes in this investigation, and the testimony of Dr. Mah, which the ALJ found to be conclusory and unsupported. Therefore, Respondents have not met their burden of proof.

c. Combination of the '511 Patent and Knowledge of One of Ordinary Skill in the Art (for the asserted claims of the '863 patent)

At issue is whether respondents waived their arguments with respect to, *inter alia*, the combination of the asserted '511 patent and knowledge of one of ordinary skill in the art.⁷⁰ The ALJ found that Respondents failed to set forth any specific combination and thus waived their argument. ID at 349-50. However, the ALJ made the finding in the

⁷⁰ In a contingent petition for review, Align asserts that the ALJ erred in finding that the '863 patent is not entitled to a priority date of December 4, 1998, based on claiming priority to the '881 provisional application, and notes that this issue was not disputed at the hearing. Align's Pet. at 40-41. Align submits that the ALJ's factual finding was incorrect because the '881 provisional application incorporates by reference the '080 patent application, which incorporates the '342 provisional application. *Id.* (citing CX-1253 at 4, '893 patent). Accordingly, Align asserts that the '881 provisional application does incorporate by reference the disclosure of the '342 provisional application to provide sufficient support for asserted claims 1 and 4-8 of the '863 patent, and therefore the '863 patent is entitled to a priority date of December 4, 1998. *Id.* (citing CX-1247C at QQ. 91-97; CX-1254C at 13). Align thus contends that ALJ's findings on this issue should be reversed.

The IA agrees with Align and submits that the ALJ does not adequately explain why a claim to a Dec. 4, 1998, priority date requires the incorporation by reference of an application filed on Jun. 20, 1997, thereby warranting review by the Commission on this issue. IA's Pet. at 7-8.

Respondents disagree with Align and submit that Align did not meet its burden for establishing an earlier priority date for the '863 patent than its filing date on the face of the patent. Respondents' Pet. at 18 (citing *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008) (patentee has the burden to establishing an earlier priority date than on the face of the patent to overcome a *prima facie* case of invalidity)).

We agree with Align and the IA that the relevant priority date for the '863 patent is Dec. 4, 1998, because it has an adequate disclosure based on the incorporation by reference of the '342 provisional application. Nevertheless, the ALJ's determination of the priority date was harmless error in view of the ALJ's finding that the '511 patent is prior art to the '863 patent regardless of whether the '863 patent may claim priority to Dec. 4, 1998. See ID at 355.

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alternative that, if Respondents did not waive this combination, the combination would render the asserted claims of the '863 patent obvious. *ID* at 350.

At the hearing, Respondents contended that the asserted claims 1 and 4-8 of the '863 patent are obvious in view of various combinations of prior art including the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 344-45. The ALJ noted that respondents do mention "knowledge of one of ordinary skill in the art" in their pre-hearing brief (section 3.5.2.2), but found that the invalidity arguments in their brief amount to a general discussion of eleven separate references with no element-by-element discussion of how those eleven references would be combined to render the asserted claims of the asserted patents obvious. *Id.* at 349 (also at 180); *see also* sections 4.1.2.2, 5.5.2.2, 6.5.2.2, 7.5.2.2, and 8.5.3.2 of Respondents' Pre-Hearing Br. (RPHB). He found rather that Respondents' pre-hearing brief only included a general reference to a "claim chart" that they would produce at the hearing. *Id.* The ALJ found that this general reference to a future claim chart is inadequate notice to Align regarding the specific prior art to be addressed and the manner in which the prior art discloses each and every element of an asserted claim. *Id.* (citing RPHG at 60-67). Accordingly, the ALJ granted Align's motion in limine number 6 and excluded the claim charts that were not specifically cited in respondents' pre-hearing brief as required by his Ground Rule 8.2.⁷¹ *Id.* (citing Tr. at 18-20).

In addition, although he noted that respondents discussed these eleven different prior art references in their pre-hearing brief at section 3.5.2.2, the ALJ found that they

⁷¹ ALJ's Ground 8.2 states that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief." *See Order No. 2* (Apr. 2, 2012).

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failed to identify any specific combinations of prior art references other than Lemchen, Kesling, and the knowledge of one of ordinary skill in the art. *Id.* (citing RPHB at 49). Having identified only these specific combinations, the ALJ found that any other combinations were waived including the combination of the asserted '511 patent and the knowledge of one of ordinary skill in the art. *Id.* at 350.

Respondents contend that their excluded claim chart was disclosed to Align as part of respondents' discovery responses and it was an exhibit to respondents' invalidity expert report. Resps. Pet. at 54. They also argue that their pre-hearing brief provided their contentions that all asserted claims were obvious and discussed the prior art in particular detail, including identifying where the disclosed subject matter was located in the prior art references. *Id.* (citing RPHB at 48-67, 97-106, 127-36, 146-54, 174-83, 205-17, 240-48). They further submit that under *Certain Mobile Devices, Associated Software, and Components Thereof* ("Mobile Devices"), Inv. No. 337-TA-744, Final ID, 2011 WL 6916539, at *103-04 (Dec. 20, 2011), their detailed disclosure complies with the ground rules and does not waive their invalidity defenses.

Complainant contends that the ALJ correctly found waiver because respondents failed to disclose this argument in their pre-hearing brief in violation of his Ground Rule 8.2. *Id.* at 30 (citing ID at 349-50).

The Commission affirms and adopts the waiver, exclusion, and limitation determinations made by the ALJ set forth in the ID at 349-50. Invalidity is an affirmative defense. 35 U.S.C. § 282. Respondents' pre-hearing briefing on invalidity states only the following with respect to the '511 patent:

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8.5.3 Obviousness under 35 U.S.C. § 103(a)

The Respondents[‘] contentions concerning obviousness described above are incorporated here. During the hearing, the Respondents intend to introduce a chart prepared by Dr. Mah that shows where each element of each asserted claim is found in the prior art reference.

* * *

8.5.3.2 The following prior art references in combination with the knowledge of one of ordinary skill in the art, and with other prior art where specifically referenced.

* * *

8.5.3.2.13 U.S. Patent No. 6,471,511 (Chishti)

Align claims a priority date of December 4, 1998 [for the ‘863 patent]. This priority date makes the other asserted patents prior art as to the ‘863 [patent]. Each of the other asserted patents discloses the following: 1) methods for producing digital models used to generate orthodontic appliances; 2) methods for providing a digital model of a patient’s dentition; 3) methods for producing a plurality of digital dentition models that represent successive orthodontic treatment stages from initial to final that are used to fabricate appliances; 4) presenting a visual image of the digital model; 5) manipulating the visual image to reposition the teeth; and 6) defining boundaries around individual teeth. These patents also disclose the use of attachment devices. One skilled in the art would also understand the use of attachment devices in light of these references.

RPHB at 205, 214.

The ALJ’s Ground Rule 8.2 states, with respect to pre-hearing briefs, that “[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn[.]” See Order No. 2. The Commission agrees with the ALJ that Respondents’ general, broad reference to the prior art as disclosing the claimed features, along with a claim chart to be purportedly presented later at the hearing does not serve to satisfy this rule. Align had no notice prior to the hearing of what arguments were to be made with respect to the asserted prior art such as: (1) where exactly in the prior art are the claim

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features disclosed; (2) what evidence would be presented; and (3) what motivation to combine such knowledge and the prior art would be presented that would lead to the claimed invention. The Commission thus affirms the ALJ's determination that Respondents' argument with respect to the '511 patent was waived and to exclude the claim chart at issue.

E. Estoppel Defense (Including Defense of Implied License or Patent Exhaustion)

Respondents argue in their petition for review that Align is estopped from asserting the patents-in-suit against them by reason of Align's withdrawal of a prior lawsuit in Texas in which Align asserted United States Patent No. 6,554,611 (the '611 Patent) and Align's issuance of a statement, which Respondents regard as a covenant not to sue (the so-called "Texas Covenant") at the time that Align withdrew its Texas lawsuit.

The ALJ, in Order No. 20, found that the Respondents had waived their right to assert a defense of estoppel or patent exhaustion because it was not previously raised in their response to the original complaint, and, assuming arguendo that the defenses were not waived, that there was no implied license of the patents-in-suit. Order. No. 20 at 23. The ALJ found that the instant situation is distinguished from the patent exhaustion cases relied on by Respondents, *TransCore* and *Leviton*, because Respondents have not established that the '880 patent and '511 patents are necessary to practice the '611 patent. *Id.* at 25 (citing *TransCore LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271, 1279 (Fed. Cir. 2009); *General Protecht Group, Inc. v. Leviton Manufacturing Co.*, 651 F.3d 1355, 1361 (Fed. Cir. 2011)). The ALJ further found that *Leviton* was not

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applicable with respect to the Texas Covenant because the asserted patents are not continuations of the '611 patent. *Id.*

The Respondents argue that the ALJ erred in his finding because the Respondents pleaded the affirmative defense of estoppel as their "Fourth Affirmative Defense" in their response to the Complaint. Resp. Pet. at 31. Respondents' Fourth Affirmative Defense stated:

Because of proceedings in the U.S. Patent and Trademark Office during the prosecution of the application that resulted in U.S. Patent Nos. 6,685,469, 6,394,801, 6,398,548, 6,722,880, 6,629,840, 6,699,037, 6,318,994, 6,729,876, 6,602,070, 6,471,511 or 6,227,850--as shown by the prosecution histories--Align is estopped from construing the claims of these patents in a way that would cause any valid claim thereof to cover or include any products that are or have been manufactured, used, sold, offered for sale, or imported by ClearCorrect, or any process used by ClearCorrect to manufacture its products.⁷²

The Respondents argue that the Fourth Affirmative Defense does not relate to prosecution estoppel, as noted by the ALJ, because the Respondents had pleaded prosecution history estoppel as a separate defense. Resp. Pet. at 32. The Respondents further argue that they could not have waived their affirmative defense of estoppel because Align was on notice of the defense based on Align's interrogatories that sought the basis of the estoppel defense. *Id.*

Align argues that the Fourth Affirmative Defense referred to by the Respondents was unrelated to the alleged defense of implied license or patent exhaustion. Align Resp. to Pet. at 10. Rather, Align argues that this affirmative defense refers exclusively to prosecution histories and claim construction. *Id.*

⁷² Response of ClearCorrect Operating, LLC to Complaint under Section 337 of the Tariff Act of 1930, as amended; Inv. 337-TA-833 (CX-1021).

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Align contends that neither *TransCore* nor *Leviton* are applicable here because unlike in *TransCore* and *Leviton*, Align never asserted the ‘611 patent against Respondents nor did they receive consideration in exchange for the agreement. *Id.* at 17. Align argues that to establish patent exhaustion, an accused infringer must show that the product sold substantially embodies the patented invention, and that Respondents cannot establish that its products embody the ‘611 patent claims or that there was an authorized sale. Align Resp. to Resps. at 18-19.

The Commission has determined to affirm and adopt the ALJ’s finding that the Respondents had waived their right to assert implied license and patent exhaustion because they were not asserted in their response to Align’s complaint. ID at 1-2; Order No. 20. The Commission requires that the affirmative defenses be pleaded with as much specificity as possible in the response to the complaint. 19 C.F.R. § 210.13(b) The Fourth Affirmative Defense upon which the Respondents base their defense of estoppel with respect to implied license and patent exhaustion is instead solely directed to Align’s prosecution of the patents-in-suit before the USPTO and does not even reference the ‘611 patent upon which its defense is based.

Aside from waiver, the Commission has determined to affirm the ALJ’s findings in Order No. 20 that the facts of the current case differ from those in *TransCore* and *Leviton* because in the Texas action, Align withdrew its complaint without a settlement agreement and Respondents provided no consideration. Order No. 20 at 25. Further, although the patents at issue are derived from a common provisional application, the resulting claims are not necessarily exhausted by operation of the ‘611 patent at issue in the withdrawn Texas suit.

PUBLIC VERSION**F. Domestic Industry - - Economic Prong**

The ALJ found that Respondents waived the right to contest domestic industry and found that Align established the economic prong of the domestic industry requirement. ID at 766-67. He concluded that Align made a significant investment in plant and equipment and significant employment of labor and capital in the United States. Specifically, the ALJ found that Align spends money on rent for a research facility and hires employees who perform research and development. *Id.* at 767. The evidence shows that Align employs over [[

]], and has paid approximately [[

]] ID at 767 (citing CX-1237C at Q 32). Align has a corporate headquarters in San Jose, California, [[]] CX-1237C, QQ.25-52. Align [[]] for its San Jose facility, [[]] ID at 766 (citing CX-1237C at Q. 27.).

Respondents argue that the ALJ erred in not allowing them to cross-examine Align's witness. Respondents' Pet. at 69. We affirm and adopt the ALJ's findings that Respondents waived this issue before the ALJ by stipulating that it would not contest domestic industry (either prong), and that Align has established that it met the economic prong of the domestic industry requirement.⁷³ ID at 766-67; Tr. at 46-48, 72-79, 619-624.

G. Domestic Industry - - Technical Prong

As stated above, the ALJ found that Respondents waived the right to contest domestic industry. He found that Align's Invisalign system satisfied representative

⁷³ We clarify that the economic prong was proven under 19 U.S.C. § 1337(a)(3)(A) and (B).

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claims of all the asserted patents except the '666 patent based on Dr. Kuo's Witness Statement. ID at 771-795.⁷⁴

1. The '487 Patent

The Respondents petitioned for review of the ALJ's finding that Align satisfied the technical prong of the domestic industry requirement based on their claim construction argument that a "treatment plan" (in claim 7) can be made only by a clinician. Resps. Pet. at 68. Because we affirm the ALJ's claim construction, we affirm the ALJ's finding that the technical prong is satisfied for the '487 patent.

2. The '863 Patent

Respondents argued in their petition that Align does not make digital models of actual dental appliances, and only makes digital models of teeth. Resps. Pet. at 68. Align responds that this argument was waived because it was not presented in a claim construction chart in a timely fashion, that the ALJ correctly held that the preamble of claim 1 is not limiting, and that Align's digital models of the teeth should be considered negative models of the aligners. Align Resp. to Pet. at 52-53. We find that Respondents waived any technical prong argument for this patent. Tr. at 46-48, 72-79, 619-624.

3. The '666 Patent

Pursuant to the claim chart set forth in the ID at 784-85, the ALJ found that Align had not made a *prima facie* showing that it practiced claim 7 of the '666 patent. ID at 787-88. The ALJ found that Dr. Kuo's witness statement did not provide any evidence

⁷⁴ The Commission adopts the ALJ's finding that the technical prong is satisfied for those patents for which there is no petition for review.

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that Align's process includes the step of "interpolating positional differences between the initial and final position of teeth." ID at 788.

Align contends that the ALJ's exclusion of factual evidence as "impermissible expert testimony" caused the ALJ to improperly rule that Align had failed to establish the technical prong of the domestic industry requirement with respect to the '666 patent. Align. Pet. at 13. Align argues that had the ALJ retained the factual testimony regarding Align's process, while striking only Dr. Kuo's conclusion, the evidence would have supported that Align's process includes "the step of interpolating positional differences between the initial and final position of teeth." *Id.* The Complainant cites the Commission's prior holding in *Certain Video Graphics Display Controllers & Prods. Containing Same*, Inv. No. 337-TA-412, Order No. 53 (Jan. 20, 1999) and a district court holding in *LaSalle Bank Nat'l Ass'n v. Nomura Asset Capital Corp.*, 2004 U.S. Dist. LEXIS 18599 (S.D.N.Y. Sept. 13, 2004) as support for the proposition that a witness's factual testimony should remain admissible even where the court determines that opinion testimony should be excluded. Align. Pet. at 16.

The IA submits that the ALJ erred in its finding that although Dr. Kuo's witness statement does not recite the exact words from the allegedly missing limitation, "his statement describes the step in sufficient detail to make a *prima facie* showing that Align practices claim 7 of the '666 patent." IA Pet. at 11. Specifically, the IA argues that the computer software, as described in Dr. Kuo's statement, "interpolates positional differences between the initial and final position of teeth" when computer software is used by Align technicians to "generate a plan wherein a tooth path is determined for motion of each tooth from an initial position to a final position." *Id.* at 11.

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The IA further argues that the ID's finding with respect to the '666 patent contradicts the finding that Align met its burden to make a *prima facie* showing that it practiced claim 1 of the '511 patent. IA Pet. at 12. The IA argues that the testimony that supported finding that Align practiced claim limitation "calculating a segmentation of the aggregate tooth paths" of the '511 patent should also satisfy the *prima facie* showing that Align practices the "step of interpolating positional differences between the initial and final position of teeth." *Id.*

The Respondents argue that Dr. Kuo's Witness Statement was the only evidence Align cites for its practice of the fourth element of claim 7 describing "interpolating positional differences" between teeth in different positions. Resps. Resp. at 5. The Respondents contend that the ALJ properly excluded Dr. Kuo's improper opinion testimony because he was never disclosed as an expert. *Id.* As such, the Respondents argue that since the relevant part of the statement was excluded, no other evidence supports the practice of "interpolation" limitation.

Respondents further disagree with the IA's comparison of the contested limitation to the '511 patent as flawed because "interpolate" is understood to mean, "To estimate a value of (a function or series) between two known values." Resps. Resp. at 7 (citing THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 915 (4th ed. 2000)). The Respondents argue that Align offered no evidence that its technicians estimate values when they "generate tooth paths" or "calculate a segmentation of tooth paths." *Id.*

The sole limitation that the ALJ found was not satisfied was the step of "interpolating positional differences between the initial and final position of teeth" of claim 7 of the '666 patent. ID at 788. We agree that the ALJ did not abuse his discretion

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with respect to excluding Dr. Kuo's concluding opinion. *See* ID at 188. However, the IA is correct to point out that the ALJ relied on Dr. Kuo's Witness Statement (and only on his Witness Statement) as evidence in finding that Align satisfied the technical prong with respect to the '511 patent. ID at 784 (citing CX-1235, Qs. 20-23). The IA is therefore correct that this same evidence (from the Witness Statement as opposed to the trial testimony) may be relied on to satisfy the technical prong with respect to the '666 patent. In our view, this same statement is equally applicable to the limitation at issue in the '666 patent. CX-1235, Q. 22 [I]

] Therefore, Align has put forth sufficient evidence to show that it practices claim 7 the '666 patent. We therefore reverse the ALJ's finding that Align has not satisfied the technical prong of the domestic industry requirement with respect to the '666 patent.

4. The '325 patent, the '880 patent, the '511 patent, and the '874 patent

The ALJ found that Align established the technical prong of the domestic industry requirement with respect to the '325 patent, the '880 patent, the '511 patent, and the '874 patent for the reasons set forth in the claim charts of the ID at 771-72, 776-77, 782, 793. None of the parties petitioned for review of satisfaction of the technical prong with respect to these patents, and we adopt the ALJ's findings with respect thereto.

PUBLIC VERSION**IV. REMEDY, THE PUBLIC INTEREST, AND BONDING****A. Remedy****1. The Recommended Determination**

The ALJ did not recommend the issuance of an exclusion order. Recommended Determination (“RD”) at 797. Instead, the ALJ recommended the issuance of a cease and desist order against CCPK and CCUS that prohibits importation (electronically or otherwise) into the United States of certain digital models, digital data, and treatment plans (for use in making dental appliances), citing Inv. No. 337-TA-383, *Certain Hardware Logic Emulation Systems and Components Thereof*, Comm’n Op. at 28 (March 1998). RD at 802. The ALJ found the presence of a “rolling” inventory in the United States because CCUS imports digital data sets on a daily basis and pays on average \$3000/day based on a monthly payment of approximately \$85,000 to CCPK. *Id.* at 803.

The ALJ observed that the Commission has granted cease and desist orders directed to electronic transmission of software in previous investigations. *Id.* at 803 (citing *Hardware Logic*). The ALJ also observed that the Commission has issued a cease and desist order against a foreign entity, Kinik Co. of Taipei, Taiwan, in *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm’n Op. (May 9, 2002).

2. Parties’ Arguments

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Align does not seek an exclusion order, and argues that the Commission should adopt the ALJ's recommendation for issuance of a cease and desist order.⁷⁵ Align Sub. at 20; Align Reply Sub. at 10. Align proposes that the language of any such order should encompass the principals and managing employees of both Respondents. Align Sub. at 20. Align argues that the Commission should issue a cease and desist order against CCPK because CCUS is at least the second company with which personnel of CCPK have worked, and an order against CCPK would better enable Align to file an enforcement action should CCPK continue its infringing conduct. Align Reply Sub. at 10.

Respondents argue that typically the complainant must prove commercially significant inventories of infringing products in the United States to justify a cease and desist order. Resps. Sub. at 19 (citing *Certain Cigarettes & Packaging Thereof*, USITC Pub. 3366, Inv. No. 337-TA-424 (Nov. 2000)). Respondents state that here there are no "inventories" of digital information at issue. *Id.* Respondents argue that the evidence does not show significant inventories of the orthodontic appliances either. *Id.*

Further, Respondents discuss the possible types of electronic communications (including telephone calls) and argue that "any cease and desist order should therefore be written narrowly to avoid excessive peripheral litigation about what transmissions and activities are prohibited." *Id.* at 20; Respondents Reply Sub. at 10. Respondents agree

⁷⁵ Align argued to the ALJ that the imposition of a "commercially significant inventory" requirement for issuing a cease and desist order would leave no practical mechanism to prevent importation in the absence of an exclusion order. Align Post-Hrg. Reply Br. at 94. Align cited the Commission Opinion in *Hardware Logic* for the notion that the purpose of issuing a cease and desist order that includes electronic transmissions is to prevent relief from being meaningless. *Id.* Align argued that the Commission has previously issued a cease and desist order against a foreign respondent in an analogous situation where that respondent's domestic distributor maintained a commercially significant inventory in the U.S. *Id.* at 96 (citing *Certain Toner Cartridges*, Inv. No. 337-TA-740, Comm'n Op. at 7-8 (Oct. 5, 2011) (citing *Certain Abrasive Products*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 2, 2002))).

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with the IA that any cease and desist order should not include CCPK. Respondents Reply Sub. at 10.

The IA agrees with the ALJ's recommendation that the issuance of an exclusion order is not appropriate in this case. IA Sub. at 10. The IA states that the Commission has previously considered and rejected requests that exclusion orders cover electronic transmissions. *Id.* (citing *Hardware Logic*, Comm'n Op. at 19-20).

The IA agrees with the ALJ's recommendation to issue a cease and desist order to CCUS. *Id.* at 11. The IA asserts that the ALJ correctly determined that CCUS has a commercially significant inventory in the United States. *Id.* at 11 (citing *Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same*, Inv. No. 337-TA-605, Comm'n Op. at 73 (June 3, 2009)). The IA states that the ALJ determined that CCUS pays CCPK approximately \$3000.00 per day, based on a monthly payment of \$85,000.00, and that this rolling daily inventory of \$3000.00 worth of digital data sets is sufficient to find that CCUS has a commercially significant inventory in the United States.

The IA disagrees with the ALJ's recommendation that a cease and desist order should be directed to CCPK because, as a matter of prudence, the Commission does not issue cease and desist orders to foreign companies that do not have a domestic inventory because it would not have an effective means of enforcing such an order. *Id.* at 12. The IA cites Commission precedent for the proposition that it is Commission practice to issue cease and desist orders only to domestic respondents, particularly in light of the difficulty of enforcing such orders against foreign entities, that cease and desist orders may ultimately be enforced by the Commission in U.S. district courts, and that it is

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inappropriate to issue one unless a party in the United States can be compelled to do some act or refrain from doing some act. *Id.* (citing *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, Comm'n Op. at 25 (July 1997); *Certain Wear Components and Products Containing Same*, Inv. No. 337-TA-644, Comm'n Op. at 22-23 (Nov. 24, 2009)); IA Reply Sub. at 10.

3. Analysis

The appropriate remedy in this case (and the only remedy requested) would be cease and desist orders directed to CCUS and CCPK.

As noted by the IA, the Commission typically imposes cease and desist orders against Respondents with domestic inventories because the ultimate mechanism for dealing with noncompliance is in district courts.⁷⁶ See 19 U.S.C. § 1337(f)(2). The ALJ found that CCUS had a “rolling” inventory of digital data sets that make up particular phases of patients’ treatment provided by CCPK to CCUS on a daily basis, which are then used by CCUS to manufacture aligners. ID/RD at 803. Although Respondents dispute whether these digital data sets may constitute inventory, the Commission nonetheless has authority to issue a cease and desist order for any violation found because the presence of a U.S. inventory is not a statutory requirement.

The Commission has issued cease and desist orders against a foreign respondent in several investigations. In *Abrasive Products*, the Commission issued a cease and desist order against Kinik Co. of Taipei, Taiwan, because the U.S. distributor, Rodel,

⁷⁶ If a person violates a cease and desist order, the Commission, in an enforcement proceeding, may replace the cease and desist order with an exclusion order, 19 U.S.C. § 1337(f)(1), or impose a penalty “of not more than the greater of \$100,000 or twice the domestic value of the articles entered or sold on such day in violation of the order.” 19 U.S.C. § 1337(f)(2). The Commission may also bring a civil action in the U.S. District Court for the District of Columbia for a mandatory injunction. *Id.*

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Inc., was not a respondent. *Abrasive Products Made Using a Process for Making Powder Preforms and Products Containing Same*, Inv. No. 337-TA-449, Comm'n Op. at 7-8 (May 9, 2000). The Commission intended to thereby bind the domestic distributor through an order directed against the foreign respondent. *Id.* The Commission also issued cease and desist orders against foreign respondents in *Certain Toner Cartridges and Components Thereof*, Inv. No. 337-TA-740. In that investigation, the Commission explained that Ninestar Tech was the same company as Ziprint, both domestic companies, and that Ninestar Tech was a subsidiary of Ninestar Image Int'l., of China, which shared a headquarters with Ninestar, also of China. In *Lighting Control Devices*, the Commission issued a cease and desist order against a foreign respondent, where a domestic reseller held the foreign manufacturers' inventories for resale in the United States, Inv. No. 337-TA-776, Comm'n Op. at 26-27 (Nov. 8, 2012).

Here, unlike *Abrasive Products*, there is a domestic respondent, CCUS. With regard to the business relationships between respondents in connection with the infringing imports, which was considered in *Toner Cartridges*, Respondents contend that CCPK is independent of CCUS. The ALJ's findings, however, show that CCPK and CCUS engage in concerted activities to produce aligners for distribution in the United States through CCPK's production of digital data sets and treatment plans that are transmitted to CCUS as set forth in the detailed findings of the ALJ in the ID.

The Commission has therefore determined that the issuance of a cease and desist order would be the appropriate remedy for the violation of Section 337 if the issuance of such an order is not precluded by the public interest factors. We consider the public interest factors in the following section.

PUBLIC VERSION**B. The Public Interest****1. Parties' Arguments**

Respondents argue that a cease and desist order would harm the public welfare. Resp. Public Interest Sub. at 2. Respondents state that in 2010, Align declared that any doctor who did not buy at least ten cases a year from Align and take the continuing education Align dictated would be stricken from Align's customer rolls and would not be sold any clear aligners. *Id.* Respondents state that Align's misconduct was addressed generally in the class action suit Case No. 3:10-cv-2010, *Leiszler v. Align Technology, Inc.*, in the United States District Court for the Northern District of California, which Align settled two years ago. *Id.* Respondents state that Dr. Willis Pumphrey founded ClearCorrect because he could not buy aligners from Align after it bought OrthoClear's assets. *Id.*

Respondents state that Align received a letter from the FDA during 2010 advising that Align had failed to disclose reports of important side effects to patients using its Invisalign system, including allergic reactions to the product. *Id.* (citing the FDA letter at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234578.htm>). *Id.* at 4. Respondents further state that Align concedes in its SEC filings that its manufacturing operations are located outside the United States. *Id.*

Align argues that cease and desist orders would not be adverse to the public interest, discussing each of the public interest factors. Align Public Interest Sub. at 2-5. Align argues that Respondents rely on vague and unauthenticated statements of doctors, that the record is closed, and that Respondents' public interest statement was untimely. Align Reply Sub. at 10.

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The IA states that Respondents do not assert any concerns that would contradict Align's assertion that the teeth positioning systems at issue are elective and not part of an essential life-saving device. IA Sub. at 12-13. The IA notes that Align attests that it has adequate capacity to service patients who want clear removable teeth positioning appliances, and that conventional braces still constitute 90% of the treatments for malocclusion. *Id.* at 13 (citing Align's Public Interest Comments at 5). As to competitive conditions in the United States economy, the IA asserts that Respondents' exit from the market would not diminish competition in the overall U.S. orthodontic market because providers and consumers would continue to have choices in the overall orthodontic market. *Id.* at 12-13. The IA notes that Align's technology makes up 10% of the orthodontic market, and that Respondents make up 10% of that market share or 1% of the overall orthodontic market. *Id.* at 12. As to the production of like or directly competitive articles in the United States, the IA notes Align's assertion that it can replace the articles covered by the cease and desist order. *Id.* at 14 (citing Align's Public Interest Comments at 4). As to United States consumers, the IA is of the view that a cease and desist order would not harm United States consumers, and that the fact that some consumers may have to pay a higher price does not outweigh the protection of intellectual property. *Id.* (citing *Certain Telecommunications Chips*, Inv. No. 337-TA-337, Comm'n Op. at 40-41 (August 1993)).

2. Analysis

After considering the record and the parties' arguments, the Commission finds that the evidence pertaining to the statutory public interest factors does not indicate that

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cease and desist orders should not be issued. However, the Commission determines to include an exemption in the cease and desist orders for existing ClearCorrect patients.

Respondents' arguments with respect to effects on public health and welfare warrant analysis both with respect to that factor and potential impact on U.S. consumers.⁷⁷ The record indicates that Align is fully capable of providing its products to all doctors seeking incremental orthodontic appliances for their patients. There is no indication that Align continues to refuse to sell to dentists after settling the class action. Indeed, Respondents note that this issue was addressed in the settlement of that litigation. Also, conventional braces account for the large majority of orthodontic treatments in the United States. As for Align's citation for failure to report side effects in 2010, the record does not reflect any continuing failure to provide such reports to the FDA or that the use of Align's products for orthodontic treatment may adversely impact patients' health. Therefore, the effects of the orders on the public health and welfare and on U.S. consumers do not indicate that the orders should not issue.

The potential effects of the orders on U.S. consumers (and possibly public health and welfare), however, warrant an exemption for activities related to treatment of patients who have already begun treatment with ClearCorrect's aligners. As the Commission has recognized in certain investigations relating to cellular telephones, *see, e.g., Personal Data and Mobile Communications Devices and Related*, Inv. No. 337-TA-710 (Exclusion Order), the Commission may balance the public interest to accommodate the needs of

⁷⁷ Respondents submitted letters from dentists on their behalf, in support of the Commission not issuing a remedial order. Resps. Sub., Attachment 13. These letters request that the dentists be allowed to continue to give their patients the option of ClearCorrect aligners. The Commission has considered these letters in considering the effect on U.S. consumers. As set forth herein, the Commission has determined that Align's system and traditional braces are both acceptable alternatives to ClearCorrect's aligners.

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U.S. consumers who require repair and replacement of existing devices. Given the ongoing nature of orthodontic treatment, we do not place a time limit on these exemptions. However, certifications and compliance reporting requirements apply to all such continuing treatments throughout the duration of treatment for existing patients. Thus, the Commission exempts repair and replacement of existing appliances from the scope of the cease and desist orders, and activities relating to treatment of patients who have already contracted for treatment with ClearCorrect as of April 10, 2014. (The one-week grace period from issuance of this order is intended to allow time for the cease and desist orders to be communicated to orthodontists and dentists.) This exemption is subject to reporting to the Commission and to a certification requirement.

As to competitive conditions in the United States economy, the record reflects that Align is able to manufacture sufficient dental appliances to meet U.S. demand for this specific type of aligner for orthodontic treatment. Moreover, the record reflects that traditional dental appliances are the predominant choice for the treatment of malocclusions and there is no indication of any adverse impacts of the cease and desist orders on these traditional appliance treatments.

As to the production of like or directly competitive articles, the record indicates that the predominant mode of orthodontic treatment in the United States is traditional braces. The record provides no indication that the orders will have any adverse effect on production of orthodontic appliances in the United States.

The Commission has therefore determined that there would be no adverse effect on the public health and welfare, competitive conditions in the U.S. economy, the

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production of like or directly competitive articles in the United States, or U.S. consumers such that the orders (with the exemption discussed above) should not be issued.

C. Bonding

The ALJ did not recommend the issuance of a bond during the period of presidential review. RD at 810.

Align states that it “does not seek review” of the ALJ’s finding that no bond is appropriate. *Id.* The IA notes that Align has not requested any bond before the Commission. IA Reply Sub. at 9.

As there is no request for a bond, the Commission has determined not to require a bond during the Presidential review period.

V. CONCLUSION

For the foregoing reasons, the Commission has determined to affirm-in-part, modify-in-part, and reverse-in-part the ID of the ALJ and to issue a cease and desist order against CCUS and CCPK.

By order of the Commission.



Lisa R. Barton
Acting Secretary to the Commission

Issued: April 9, 2014

PUBLIC VERSION**DISSENTING VIEWS OF COMMISSIONER DAVID S. JOHANSON**

It is a question of first impression whether the electronic transmission of digital data into the United States constitutes importation of an “article” within the meaning of Section 337(a)(1)(B) of the Tariff Act of 1930. The Commission majority broadly interprets the statute to allow it to exercise jurisdiction and find a violation by treating electronic transmission of data as an “article.” As this interpretation does not address Congress’s delegation of authority to the Commission, ignores Section 337’s remedial scheme, and contradicts the federal courts’ interpretation of “articles,” I respectfully dissent.¹

1. The Commerce Clause of the United States Constitution empowers Congress to “regulate commerce with foreign nations” and to “lay and collect taxes, duties, imposts, and excises.” U.S. Const. Art. I, § 8, cl. 1-3. Under that authority, Congress has passed into law numerous federal statutes, including the Tariff Act of 1930, as amended. Section 337 was originally enacted as Section 316 of the Tariff Act of 1922, one of the so-called “flexible tariff” provisions of that Act. As a trade act, Section 337 is not meant to remedy every unfair act in every context, but rather is directed to remedy those acts in the context of the statutory framework established by Congress for importation into the customs territory of the United States.² Thus, Section 337 is not the international extension of our patent, copyright, and

¹ Align bears the burden of proof under the Administrative Procedure Act to show that electronic transmissions are “articles” within the meaning of Section 337. 5 U.S.C. § 556(d) (“Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.”). Specifically, Align has the burden of showing Congress intended to cover digital transmissions under Section 337. Align has failed to meet that burden.

²As discussed below, Align and the majority assert Section 337 is a remedial statute and should be broadly construed. But the legislative history makes clear that the only part of Section 337 that should be broadly construed is “unfair methods of competition and unfair acts” in Section 337(a)(1)(A), not the portion of the statute at issue here. *See, e.g.*, Report, S. Rep. 67-595 at 3 (1922), 62 Cong. Rec. 5879 (1922). Indeed, the “unfair competition” part of the statute was

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trademark laws, but has restrictions that stem from the fact that it is, first and foremost, a trade law. *See, e.g., Schaper Mfg. Co. v. ITC*, 717 F.2d 1368, 1373 (Fed. Cir. 1983) (rejecting broader construction of the domestic industry requirement); *Corning Glass Works v. ITC*, 799 F.2d 1559, 1566 (Fed. Cir. 1986) (rejecting broader construction of the injury requirement); *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1355 (Fed. Cir. 2008). Indeed, the statute provides that the remedies it permits are in addition to other provisions of law. 19 U.S.C. 1337(a)(1). Thus, Section 337 provides a customs remedy in addition to the remedies that can be obtained from the courts. Align is currently seeking relief from the courts.³

Section 337's requirements—and in particular, what it means to be an imported “article”—therefore must be informed by Congress's understanding of the scope of the enacted United States trade laws. The ITC is a creature of statute and must find authority for its actions in its enabling statute. *See Vastfame Camera, Ltd. v. ITC*, 386 F.3d 1108, 1112 (Fed. Cir. 2004). It therefore is simply incorrect to say that the Commission has broad authority except as expressly limited by Congress. Absent clear indications to the contrary, it makes little sense to interpret Section 337 in a way that differs from the interpretation of other trade statutes. Besides lying closer to Congress's intent, a consideration of the trade laws in unison reduces the

never at issue here as this case was brought under the specific patent provisions of Section 337(a)(1)(B). I further note that denominating a statute as “remedial” does not permit an agency or tribunal to add to a statute. *Fortin v. Marshall*, 608 F.2d 525, 529 (1st Cir. 1979) (citing *United Shoe Workers of America, AFL-CIO v. Bedell*, 506 F.2d 174, 187 (D.C. Cir. 1974); *U.S. EEOC v. AIC Security Investigations, Ltd.*, 55 F.3d 1276, 1282 (7th Cir. 1995) (“A liberal construction does not mean one that flies in the face of the structure of the statute.”)). It is argued that the term “that infringe” which follows “articles” in Section 337(a)(1)(B)(i) modifies “articles” so that the term covers electronic transmissions. However, a modifier narrows its subject; it does not broaden it.

³ The parties are involved in a civil action in the Southern District of Texas, which has been stayed during the Commission investigation. *Align Technology, Inc. v. ClearCorrect, Inc., ClearCorrect Operating, LLC, and ClearCorrect Holdings, LLC*, No. 4:11-cv-00695 (Jury Demanded), Order (May 10, 2012).

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possibility of inconsistent or contradictory treatment of different imports. Therefore, to understand Section 337, it is important to consider, for example, the Harmonized Tariff Schedule of the United States (HTSUS). Indeed, Section 337 specifically references the HTSUS. *See* 19 U.S.C. § 1337(m) (defining the United States to mean the customs territory of the United States as defined in general note 2 of the HTSUS).⁴

Under the HTSUS, tangible items are subject to tariff⁵ as has always been the case with the customs laws of the United States. This comports with the plain understanding of the term in the context of the statute; namely, “articles” are physical things.⁶ *See Dolan v. United States*

⁴ The Commission routinely requires the complainant to provide the applicable HTS number for the articles subject to a Section 337 investigation.

⁵ The dutiable lists or schedules of the Tariff Act of 1930, set forth in Title I, were replaced in 1963 by the Tariff Schedule of the United States, (the “TSUS”), Pub. L. 87-456. The legislative history of the TSUS includes the Tariff Classification Study Submitting Report, which accompanied the proposed revisions to the tariff laws. In that Report, the Commission wrote “General headnote 5 sets forth certain intangibles which, under various established customs practices, are not regarded as articles subject to treatment under the tariff schedules.” *Id.* at 18. In this connection, the original TSUS explicitly excepted electricity from the scope of the tariff schedules. General headnote 5(c). The TSUS was in turn replaced by the Harmonized Tariff Schedule of the United States (“HTSUS”), pursuant to the Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418 § 1206, 102 Stat. 1151, codified at 19 U.S.C. § 3006. The HTSUS includes a heading for electrical energy but provides that electrical energy shall enter duty free and is not subject to entry under Section 484 of the Tariff Act of 1930; rather, the HTSUS provides that electrical energy is subject to entry under regulations to be prescribed by the Secretary of the Treasury. Compare HTSUS 2716 with HTSUS General Headnote 3(e)(iii) and Headnote 6(b) to Chapter 27. While the amendments subsequent to 1930 to the tariff schedules may or may not be relevant to the interpretation of Section 337, it is clear that the original tariff schedules only included tangible items and that the HTSUS excludes telecommunications transmissions and business data as intangibles (and even excludes electric energy from the entry requirements of Section 484 of the Tariff Act of 1930).

⁶ When looking to the plain meaning of “article” based on a reliance on certain dictionary definitions from 1922 to 1930 at the time of the enactment of Section 337 as the Supreme Court requires us to do, it must not be viewed in the abstract. Rather, one should look to the statute when read in the context of other trade laws to determine which definition fits within that context. *Dolan v. United States*, 546 U.S. at 486. Under that analysis “article” means a tangible good. Numerous definitions were submitted to support a “plain meaning” construction of the

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Postal Service, 546 U.S. 481, 486 (2006) (“The definition of words in isolation, however, is not necessarily controlling in statutory construction. A word in a statute may or may not extend to the outer limits of its definitional possibilities. Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, and consulting any precedents or authorities that inform the analysis.”). In fact, the only clear reference to Customs’ authority to regulate electronic transmission of digital data strongly suggests Congress did *not* intend for Section 337 to remedy electronic transmissions. Congress explicitly exempted electronic transmissions as a good from the tariff schedule. *See* HTSUS General Headnote 3(e)(“For the purposes of general note 1 – (ii) telecommunication transmissions … are not goods subject to the provisions of the Tariff schedule.”). Thus, Congress has specifically limited Customs’ authority to regulate or lay and collect taxes, and/or duties on electronic transmissions. *Id.* There is nothing in the legislative history of Section 337 to suggest that the Commission’s authority exceeds Customs’ in this regard.

term “article,” and the majority of such definitions suggest some tangible quality (or are at best ambiguous): (1) “Something considered by itself and as apart from other things of the same kind or from the whole of which it forms a part; also, a thing of a particular class or kind; as, an *article* of merchandise; salt is a necessary *article*” (Harris, Webster’s New International Dictionary of the English Language at 131, G. & C. Merriam Co. (1924)); (2) “A particular object or substance; a material thing or class of things; as, an *article* of food” (Funk, New Standard Dictionary of the English Language, Funk & Wagnalls Co. at 162 (1929)); (3) “a particular thing; item” (Webster’s New International Dictionary, 2d. Edition (1927)); (4) “a particular thing” (Funk & Wagnall’s Concise Standard Dictionary of the English Language, 2d. Edition (1929) and Fowler, H. W., Concise Oxford dictionary of Current English, 2d. Edition (1929)); (5) “a particular object or substance; a material thing or class of things” (Funk & Wagnall’s College Standard Dictionary of the English Language, 1st edition (1929)). Relatedly, the Federal Circuit relied on a definition of “article” in Webster’s Third New International Dictionary (a more recent edition of Webster’s) in interpreting 35 U.S.C. § 271(g), which was enacted in 1988. “Article” is there defined as “one of a class of *material things . . . piece of goods; COMMODITY.*” *Bayer AG v. Housey Pharmaceuticals, Inc.*, 340 F.3d 1367, 1372 n.4 (Fed. Cir. 2003) (emphasis added by Federal Circuit).

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Other related trade laws also have been limited to tangible goods. For example, under the previous countervailing duty law, Section 303 of the Tariff Act of 1930 (now repealed), the term “merchandise” was limited to tangible items. *See Preliminary Affirmative Countervailing Duty Determination: Certain Computer Aided Software Engineering Products from Singapore*, International Trade Administration, Department of Commerce (Commerce), 55 Fed. Reg. 1596 (January 17, 1990). In that case, Commerce rejected the argument that the imported software should be analyzed exclusively in terms of its (intangible) intellectual property and be considered merchandise under Section 303. Commerce concluded that it is the tangible medium, and not the intangible software, which can give the imported goods their characteristics as merchandise under Section 303. There, software on a tangible medium was an article or “merchandise,” but electronic transmission of software would not have been. Section 303 was, like Section 337, part of Title III of the Tariff Act of 1930. It specifically referenced an “article or merchandise.” The use of the terms article and merchandise interchangeably suggests they should be afforded the same meaning, and both appear in the same provision of the Tariff Act of 1930. Again, there is no indication in the legislative history that Congress intended to construe “article” differently in Section 337 as compared to the rest of Title 19. In sum, there is nothing in related trade acts to suggest inclusion of anything other than tangible articles.

2. There are additional indications within Section 337 itself that support an interpretation of “articles” that does not include electronic transmissions. Congress created Section 337 to remedy unfair practices in the importation of goods and provided specific remedies—central of which is exclusion from entry. The statute’s references to “entry”⁷ are

⁷ Citations to interpretations of terms in unrelated statutes or cases that generally concern the term “importation” and “articles of commerce” untied to Section 337 offer little guidance. *See*

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found in eight of the fourteen subsections of Section 337 and provide various remedies directed toward articles specifically: exclusion from entry and seizure and forfeiture orders. *See* 19 U.S.C. § 1337(d), (e), (i), (j) (e.g., “articles concerned” be excluded from entry; “attempted entry”; and “denial of entry”). This focus on how “articles” obtain “entry” into the United States is no accident. The concern with entry reflects Congress’s explicit choice to attack the problem of articles that violate Section 337 through established Customs entry procedures (*i.e.*, Section 484 of the Tariff Act of 1930 (19 U.S.C. § 1484) and associated Customs regulations 19 U.S.C. § 1484(c)(1) (Entry).⁸ It is this remedial scheme that was adopted in Section 337.

That scheme contemplates only tangibles as “articles.” Electronic transmissions do not arrive at ports of entry, are incapable of being held in Customs custody, cannot be presented to Customs, and therefore can never be refused or denied entry. An exclusion order directed against electronic transmissions could not only have no effect within the context of Section 337—it simply would make no sense as it would not be enforced. Moreover, to define “articles” as including electronic transmissions would render much of Section 337 meaningless because the definition cannot be applied to all or part of eight of the fourteen subsections of Section 337. *See* *United States v. Ron Pair Enterprises, Inc.* 489 U.S. 235, 242 n.5 (1989) (a definition should be

Cedar Rapids Community School Dist. V. Garret F. ex rel. Charlene F., 526 U.S. 66, 78 n.10 (1999).

⁸ The procedure may be briefly described as follows: Once merchandise arrives at a port of entry, it is regarded as imported and comes under Customs’ custody. In order to obtain release from Customs’ custody into the “United States,” *i.e.*, the customs territory of the United States, the importer must “make entry,” *i.e.*, present certain documentation to Customs so that Customs may determine whether the merchandise may be admitted into the customs territory of the United States and, if admissible, what duties, if any, are applicable. It is a hallmark of this process that both the merchandise and entry documentation are presented to Customs before Customs may permit the merchandise to enter the customs territory of the United States. 19 U.S.C. § 1484(c)(1) (Entry); *see, generally, Ernesto F. Rodriguez, Inc. v. United States*, 65 Cust. Ct. 163, C.D. 4072 (1970); *United States v. Mussman & Shafer*, 40 C.C.P.A. 108 (1953); *Wilcon v. United States*, 13 Cust. Ct. 96, C.D. 876 (1944).

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consistent with and give effect to the entire statute). For example, Section 337(i) discusses “attempted entry” of the article. It makes little sense to say electronic data is the subject of “attempted entry”—it was either transmitted or it was not. This provision only reasonably applies to attempts to import physical goods. Congress has chosen not to regulate electronic transmissions or other forms of data⁹ through Custom’s entry procedures. An interpretation of “article” that captures that which Congress expressly denied Customs from regulating would be entirely inconsistent with the remedial scheme of Section 337 established by Congress.

In addition, the term “article” should be construed to have the same meaning throughout the statute, regardless of the remedy. *See Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (“The substantial relation between the two programs presents a classic case for application of the ‘normal rule of statutory construction that “identical words used in different parts of the same act are intended to have the same meaning?’”’) (citations omitted). It would be improper to define “article” differently depending on whether one is referring to an exclusion order or a cease and desist order. Indeed, to define “article” in such a way that a separate regime is created for electronic transmissions consisting of only select portions of Section 337 would run afoul of the remedial framework established by Congress. For example, cease and desist orders may be issued “in lieu of” exclusion orders. The legislative history makes clear that cease and desist orders were added to provide a less draconian remedy than exclusion orders, and our reviewing court has referred to cease and desist orders as a “softer remedy” than exclusion orders. *Textron, Inc. v. USITC*, 753 F.2d 1019, 1029 (Fed. Cir. 1985); *see* S. Rep. 93-1298 at 198 (1974). This is laid out by the language of the statute, which provides that cease and desist orders can be

⁹ HTSUS General Headnote 3(e)(ii) and (iii) (emphasis added) (2012). For the purposes of general note 1 the following are also exempt: (ii) telecommunication transmissions... (iii) records, diagrams and **other data** with regard to any business, engineering or exploration operation whether on paper, cards, photographs, blueprints, tapes or **other media**.

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replaced with exclusion orders. If “articles” were defined to include electronic transmissions, such replacement would not be possible. Indeed, that provision demonstrates that the definition of “articles” for Section 337(f) must be the same as the rest of the statute; otherwise the provision for replacement would be rendered a nullity and read out of the statute.¹⁰ Due to the nature of electronic data transmissions, for example, an exclusion order’s requirement that goods be “permitted entry” if a respondent posts a bond makes little sense when such transmissions cannot be subject to the Customs entry and other port requirements. If issuing an exclusion order against electronic data is incompatible with this scheme then, according to the express statements of the statute, cease and desist orders solely based upon electronic transmissions should not issue either.

3. The federal courts also have provided significant guidance on the meaning of the term “article” that strongly suggests that it should not include intangibles for the purposes of the importation requirement.

In *Bayer v. Housey*, the Federal Circuit analyzed Section 337, stating that Section 337 does not cover intangibles.¹¹ 340 F.3d at 1374. In *Bayer*, the question before the Federal Circuit

¹⁰ Critically, this does *not* prevent the Commission from including electronic transmissions within the scope of a cease and desist order, as in *Hardware Logic*, in order to prevent circumvention of its remedial orders after it has already found a violation of Section 337. This possibility is based on the Commission’s broad remedial authority. It does not depend on whether electronic transmissions are “articles.”

¹¹ Multiple courts are in accord. For example, in interpreting the term “article” in a previous Tariff Act, the Supreme Court held that it “applied to almost every separate substance or material, whether as a member of a class, or as a particular substance or commodity.” *Junge v. Hedden*, 146 U.S. 233, 238 (1892). The Court of Customs and Patent Appeals (the “C.C.P.A.”), the predecessor to the Federal Circuit, explained that the term “articles” is used hundreds of times in most tariff statutes, with narrower or broader meanings, but that in providing a dutiable list in Title I of the Tariff Act of 1930, it means, in a broad sense, “any provided-for substance, material or thing of whatever kind or character.” *United States v. Eimer & Amend*, 28 CCPA 10, 12 (1940). Thus, according to the C.C.P.A., the dutiable schedule of the Tariff Act of 1930

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was whether the term “a product which is made by a [patented] process” in 35 U.S.C. § 271(g) includes information as a result of that process. The court held that it does not. To arrive at that conclusion, the court looked to Section 337 as section 271(g) “was designed to provide new remedies to supplement existing remedies from the International Trade Commission (“ITC”) under 19 U.S.C. § 1337 (2000).”¹² *Id.* at 1373. Indeed, in expanding infringement to include section 271(g), Congress “recognized the availability of redress from the ITC, but noted that the remedies available thereunder were insufficient to fully protect the owners of process patents.” *Id.* at 1374. The court stated that the “legislative history suggests that section 271(g) was intended to address the same ‘articles’ as were addressed by section 1337, but to add additional rights against importers of such ‘articles.’” *Id.* at 1374. It then stated:

We recognize that section 1337 covers both articles that were “made” and articles that were “produced, processed, or mined.” While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

Id. at 1374 n.9. While the Federal Circuit decision concerned section 271(g), that decision was based on the court’s understanding that Section 337 does not cover intangible information. Indeed, in the absence of that understanding, there would be little or no basis for the Court’s holding regarding section 271(g), thereby indicating that this discussion should not be discounted as dicta.

represents the broadest possible sense of the term “article.” As noted above, the schedule lists tangible goods.

¹² The court specifically noted Section 337(a)(1)(B)(ii) (referring to “articles that – are made, produced, processed or mined under . . .”), but also referred to Section 337(a)(1)(A) (referring to “unfair acts in the importation of articles”). *Id.* at 1373-74. The court had previously noted that the term “article” refers to “one of a class of material things . . . piece of goods; commodity.” *Id.* at 1372 n.4.

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The Federal Circuit further clarified that the creation of electronic data cannot be considered to be “manufactured” or a “product” under section 271(g) in *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1323-24 (Fed. Cir. 2005). In that case, the plaintiff argued that, while *Bayer* might address electronic data in the abstract, the defendant’s intangible e-mail packets were actually “manufactured” and “imported” due to the specific packaging of the data by the defendant. *Id.* The court disagreed, holding that “transmission of information … does not entail the manufacturing of a physical product,” so section 271(g) did not apply. Similarly, the complainant in this case cannot escape the requirements of Section 337 through the argument that the respondent’s data is packaged in any specific format and so is “manufactured.”

The Federal Circuit also has suggested that “articles” are limited to “tangible articles” in interpreting the portion of Section 337 dealing with the domestic industry requirement. Under Section 337(a)(3), “an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent,” certain investments. The court interpreted this language in several cases this year. In *Interdigital Communications, LLC v. International Trade Commission*, 707 F.3d 1295 (Fed. Cir. 2013) (opinion on denial of rehearing), the court extensively examined the legislative history of Section 337(a)(3).¹³ The court held that the domestic industry requirement is met by goods manufactured outside the United States as long as there is substantial investment in licensing in the United States. *See id.*

¹³ The court restated this point in *Motiva* holding that licensing programs only meet the need that there be “articles protected by the patent” when those programs “encourage adoption and development of articles that incorporate… patented technology.” *Motiva, LLC v. International Trade Commission*, 716 F.3d 596, 600 (Fed. Cir. 2013). In *Motiva*, the Federal Circuit relied not only on *Interdigital* but also on *John Mezzalingua Assocs. v. Int’l Trade Comm’n*, 660 F.3d 1322 (Fed. Cir. 2011) in which it noted that the “Commission is fundamentally a trade forum, not an intellectual property forum” and holding that “litigation expenses directed at preventing instead of encouraging *manufacture of articles* incorporating patented technology does not satisfy the domestic industry requirement of Section 337.” *Id.* at 600 (emphasis added).

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at 1303-04. But the court also held that licensing activity only meets the domestic industry requirement if there are “articles protected by the patent.” *Id.* at 1300-04. The court held that the legislative history made clear “that a sufficiently substantial domestic industry will need to license its technology *to a manufacturer somewhere*; they do not say that the manufacturer must be domestic.” *Id.* at 1303 n.4 (emphasis added). This suggests that the “articles protected by the patent” are physical articles manufactured somewhere. Recently, in *Microsoft Corp. v. Int'l Trade Comm.*, 731 F.3d 1354, 1362 (Fed. Cir. 2013)(emphasis added), the court noted that “[a] company seeking section 337 protection must therefore provide evidence that its substantial domestic investment … relates to an *actual article* that practices the patent, regardless of whether or not that article is *manufactured* domestically or abroad.”

In sum, the Federal Circuit has indicated an “article protected by the patent” under Section 337(a)(3) is a physical good—and specifically a good that can practice the patent. Indeed, it is difficult to see how abstract data can be said to be “practicing the patent.” The key point is that the word “article” appears both in the domestic industry requirement of Section 337(a)(3) and in the importation requirement of Section 337(a)(1)(b). Accordingly, the same word found in adjoining statutory sections should be given the same meaning. *See Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2004-05 (2012) (“[I]t is a ‘normal rule of statutory construction’ that ‘identical words used in different parts of the same act are intended to have the same meaning.’”). It is contrary to canons of statutory construction to construe the “articles” being “protected” one way and the “articles” causing the harm another way.

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Nor do prior decisions of this Commission compel a different interpretation of “articles.”¹⁴ For example, in *Hardware Logic*,^{15,16} the Commission determined to include electronic transmission of the respondents’ infringing software in a cease and desist order (but not an exclusion order). *Id.* at *11. Importantly, the allegedly infringing import was not an electronic transmission in that investigation, but rather a (tangible) emulation device system, which included software. It was argued that some systems were imported without software. It was also argued that some of the software was imported on a disk or electronically transmitted into the United States. As to the software imported as part of an infringing emulation system and on a disk, which clearly could be imported or excluded by Customs from importation, the

¹⁴ Most recently, in the related proceeding, *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Public Comm'n Op. (Feb. 19, 2013), the Commission reaffirmed the holding of *Hardware Logic* that the Commission may craft its cease and desist orders and consent orders to prohibit the importation of electronic transmissions after a determination of violation. As the Commission noted in its submission to the Federal Circuit on appeal, the 562 investigation did not address whether an electronic transmission of digital data is an article in the context of violation. On page 7 of its opinion in *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), the Commission stated “[T]he Commission has held that it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States,” *Id.* (citing *Certain Hardware Logic Systems and Components Thereof (“Hardware Logic”)*, Inv. No. 337-TA-383). The citation includes the following parenthetical as to the holding in *Hardware Logic*: “(stating that the Commission has the legal authority to issue a remedial order that covers electronic importations, and issuing a cease and desist order that covered electronic importation).” Thus, *Dental Appliances* confirms that the Commission’s broad authority to fashion a remedy (covering acts which might not themselves be a violation of the statute) can justify a cease and desist order addressing electronic transmissions in an appropriate case.

¹⁵ *Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, Commission Determination (U.S.I.T.C. 1998), 1998 WL 307240.

¹⁶ Similarly, in *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-510, the accused products were hardware with versions of source code. Final ID at 57 (May 9, 2005). In *Viruses*, the Commission stated that it was following *Hardware Logic*, and prohibiting electronic transmissions in the cease and desist order but not in the exclusion order. Comm'n Op. at 4-5 (Aug. 23, 2005).

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Commission entered an exclusion order covering those emulation systems found in violation.

See id. at *7-9. But the Commission was concerned that its remedy could be circumvented if it did not preclude transmission of the software running those emulation systems. *Id.* at *15.

To avoid circumvention of its orders of a Section 337 violation—based on importation of physical articles—the Commission recognized that its remedial authority to issue cease and desist orders could cover electronic transmissions of data. *Id.* at *16. Put another way, the Commission’s remedy may go beyond merely stopping the actual violation that triggered the Commission’s jurisdiction and also include “reasonably related” acts that would result in circumvention of the Commission’s order. *See FTC v. Mandel Bros.*, 359 U.S. 385, 392-93 (1958) (permitting FTC to prohibit like and related acts of misbranding with amended wording of cease and desist order).¹⁷ But the fact that the Commission has broad remedial power does not expand the Commission’s ability to change activity that is not a violation of Section 337 into one that is. To the extent that others have interpreted the Commission as holding otherwise, those interpretations stretch that decision too far.¹⁸

4. While the majority carefully provides a thoughtful analysis of the statute and law to come to a contrary conclusion, I must respectfully disagree.

¹⁷ The language of Section 337 closely resembles the language of the FTC Act, 15 U.S.C. § 45.

¹⁸ One such interpretation is found in *Former Employees of Computer Sciences Corp. v. United States Secretary of Labor*, 414 F. Supp. 2d 1334 (C.I.T. 2006), but *cf. Woodrum v. U.S.*, 737 F.2d 1575 (Fed Cir. 1984) (Federal Circuit affirmed the CIT’s determination that the term “article,” under section 222(3) of the Trade Act of 1974, does not cover activity that fails to create or manufacture a tangible commodity, or transforming an existing product into a new and different article). This decision concerns whether former employees ought to receive certain benefits under 19 U.S.C. § 2272(a)(2)(A) (“Trade Adjustment Assistance”). In interpreting that statute the CIT characterized our decision in *Hardware Logic*, as holding that “software [is] an article of importation regardless of its mode of importation.” *Id.* at 1342. This 2006 decision is not binding on the Commission but is instead binding on the Department of Labor and appears inconsistent with other authority.

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The majority states that its “task is to determine whether the phrase ‘importation … of articles’ encompasses this modern form of international commerce, or should be understood as limited to the kinds of international transactions in existence when the statute was first enacted” (at 54). To be sure, it is appropriate to apply a statute to new technology when that technology falls within the words of the statute. No one would argue that Section 337 is frozen to cover only items that existed in 1930. But we are also bound by the words of statute, and we should examine new technologies in light of the statute and regulations as written. The Supreme Court’s decision in *Fortnightly Corp. v United Artists Television, Inc.*, 392 U.S. 390 (1968), highlights this principle.

In *Fortnightly*, the owners of copyrighted motion pictures brought suit against community antenna television systems that acted as large antennas to receive television broadcasts for communities that had trouble picking up the broadcasts using standard household receivers. *See id.* at 391. The Supreme Court acknowledged that it “must read the statutory language of 60 years ago in the light of drastic technological change.” *Id.* at 396. But the Court did not divorce such a reading from the language of the statute and held that those transmissions could not be understood to violate the enumerated rights listed in the Copyright Act. *See id.* 400-01. In doing so, the Court rejected the argument that it “accommodate various competing considerations of copyright, communications, and antitrust policy,” stating “[w]e decline the invitation. That job is for Congress. We take the Copyright Act of 1909 as we find it.” *Id.* at 401.¹⁹ In this instance, extending the term “article” in Section 337 to cover electronic

¹⁹ Congress subsequently took up that job in enacting the Copyright Act of 1976 to cover such situations. *See WGN Continental Broadcasting Co. v. United Video, Inc.*, 693 F.2d 622, 624 (7th Cir. 1982).

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transmissions of digital data would be an over extension of the statute. *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1355 (“The ITC is a creature of statute, and must find authority for its actions in its enabling statute.”).

Moreover, based on its goals of preventing every type and form of unfair practice, the majority finds that electronic transmissions must be covered under Section 337 by holding that “the meaning of ‘articles’ extends to all imported items of commerce as to which a finding of infringement by a patent, trademark, copyright or protected hull design may be sustained (provided that all other requirements of the statute are met).” Op. at 42. But defining “article” in Section 337 in terms of what infringes raises the question of what the definition of “article” is.²⁰ This definition does not account for the numerous cases in which infringement is clearly demonstrated, but no violation of Section 337 is found based on additional statutory requirements contained in Section 337, e.g., 1337(a)(2), (3). If there can be acts of infringement that do not yield a violation of Section 337, then one should avoid treating infringement and Section 337 as coextensive.

Indeed, the “other requirements of the statute” also use the term “article”; it does not appear only in the phrase “articles that infringe” in Section 337(a)(1)(B). It is also found in the phrases “exclusion of articles from entry,” § 337(d), “articles … be seized,” § 337(i), “previously attempted to import the article,” § 337(i)(1)(A), and “consignee of any article,” § 337(i)(4). As explained above, those phrases lack clear meaning if “article” includes electronic transmissions. Thus, any interpretation focused solely on the phrase “articles that infringe” without consideration of those other uses of the word in this trade statute is improper.

²⁰ See n. 2 supra.

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Finally, an alternative definition of “article” that “encompasses such items as are bought and sold in commerce and that are imported into the United States, regardless of the mode of importation,” (Op. at 41) appears overly broad. In fact, there are things that are not “articles” under anyone’s definition, which “could be bought and sold”—for example a service.

Ultimately, I am sympathetic to protecting against all manner of unfair trade actions. The Commission, however, is bound by statute, and I am reluctant to broaden the definition of “article” as suggested by Align and the majority without an act of Congress.

5. In sum, the plain language of the statute, its interplay with other trade statutes, the lack of guidance in the statute’s legislative history, and the statute’s prior judicial interpretation all lead to the same place: Congress did not delegate to the Commission the authority to remedy importation of “articles” based only on electronic data transmitted into the United States. Under the facts in this investigation, the activities of the respondents may be unfair business practices and may even deserve a remedy in some other forum. But it is not clear that electronic transmissions of data are “articles” under Section 337, and absent such clarity the Commission should defer to Congress and should err on not assuming new powers. So far, Congress has not taken this step. *See Schaper Mfg. Co. v. International Trade Comm’n*, 717 F.2d at 1373 (“If, as appellants suggest, present-day ‘economic realities’ call for a broader definition to protect American interests (apparently including many of today’s importers) it is for Congress, not the courts or the Commission, to legislate that policy.”). For these reasons, I respectfully dissent and hold that due to a lack of importation of “articles” within the meaning of Section 337 there can be no violation of Section 337 in this investigation, and, therefore, do not join the remainder of the Commission’s opinion.

**CERTAIN DIGITAL MODELS, DIGITAL DATA, AND
TREATMENT PLANS FOR USE, IN MAKING
INCREMENTAL DENTAL POSITIONING ADJUSTMENT
APPLIANCES, THE APPLIANCES MADE THEREFROM,
AND METHODS OF MAKING THE SAME**

337-TA-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Vu Bui, Esq., and the following parties as indicated, on **April 10, 2014**.



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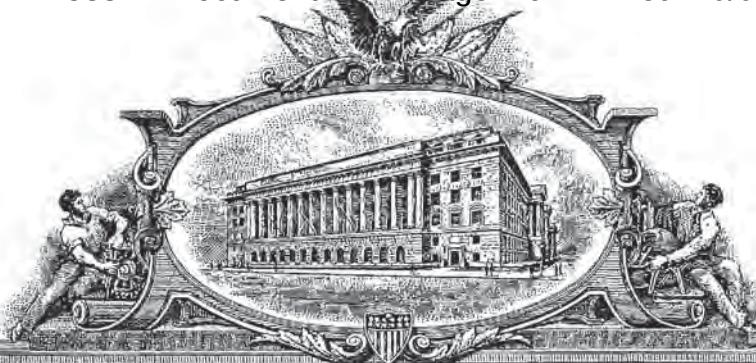
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December 21, 2011

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
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U.S. PATENT: 6,217,325

ISSUE DATE: April 17, 2001

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W. MONTGOMERY
Certifying Officer



A2921



US006217325B1

(12) **United States Patent**
Chishti et al.

(10) **Patent No.:** US 6,217,325 B1
(b5) **Date of Patent:** *Apr. 17, 2001

(54) **METHOD AND SYSTEM FOR INCREMENTALLY MOVING TEETH**

(75) Inventors: Muhammad Chishti, Menlo Park; Apostolos Lerios, Stanford; Brian Freyburger, Palo Alto; Kelsey Wirth, Menlo Park; Richard Ridgley, Los Altos, all of CA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: Apr. 23, 1999

Related U.S. Application Data

(62) Division of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.

(60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) Int. Cl.⁷ A61C 3/00

(52) U.S. Cl. 433/24; 433/213; 433/215

(58) Field of Search 433/24, 213, 215

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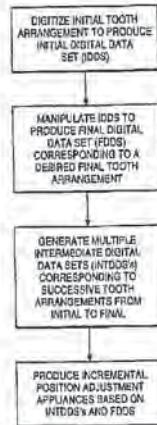
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(57) ABSTRACT

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

26 Claims, 9 Drawing Sheets



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**METHOD AND SYSTEM FOR
INCREMENTALLY MOVING TEETH**

The present application is division of application Ser. No. 08/947,080, filed Oct. 8, 1997, now U.S. Pat. No. 5,975,893, which is a continuation of provisional Application No. 60/050,342; filed on Jun. 20, 1997, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically scheduled with the orthodontist, dentist, and/or X-ray laboratory so that X-rays and photographs of the patient's teeth and jaw structure can be taken. Also during this preliminary meeting, or possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well bonded to the teeth.

The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontics as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tightening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many

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visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

2. Description of the Background Art

Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, La. 70125, and Tru-Tain Plastics, Rochester, Minn. 55902. The manufacture of orthodontic positioners is described in U.S. Pat. Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.* 30:673-680; Cureton (1996) *J. Clin. Orthodon.* 30:390-395; Chiappone (1980) *J. Clin. Orthodon.* 14:121-133; Shilliday (1971) *Am. J. Orthodontics* 59:596-599; Wells (1970) *Am. J. Orthodontics* 58:351-366; and Cottingham (1969) *Am. J. Orthodontics* 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics* 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459.

U.S. Pat. Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Pat. Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

SUMMARY OF THE INVENTION

The present invention provides improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally

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reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, certain of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

Systems according to the present invention will include at least a first appliance having a geometry selected to reposition a patient's teeth from the initial tooth arrangement to a first intermediate arrangement where individual teeth will be incrementally repositioned. The system will further comprise at least one intermediate appliance having a geometry selective to progressively reposition teeth from the first intermediate arrangement to one or more successive intermediate arrangements. The system will still further comprise a final appliance having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. In some cases, it will be desirable to form the final appliance or several appliances to "over correct" the final tooth position, as discussed in more detail below.

As will be described in more detail below in connection with the methods of the present invention, the systems may be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single package or system. The order in which the appliances are to be used will be clearly marked, (e.g. by sequential numbering) so that the patient can place the appliances over his or her teeth at a frequency prescribed by the orthodontist or other treating professional. Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller, successive steps while still reducing the time spent by the treating professional with the individual patient. Moreover, the ability to use polymeric shell appliances which are more

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comfortable, less visible, and removable by the patient, greatly improves patient compliance, comfort, and satisfaction.

According to a method of the present invention, a patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment appliances in the patient's mouth. Conveniently, the appliances are not affixed and the patient may place and replace the appliances at any time during the procedure. The first appliance of the series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. After the first intermediate arrangement is approached or achieved, one or more additional (intermediate) appliances will be successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). The treatment will be finished by placing a final appliance in the patient's mouth, where the final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to the final tooth arrangement. The final appliance or several appliances in the series may have a geometry or geometries selected to over correct the tooth arrangement, i.e. have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e. to permit some movement of individual teeth back toward their pre-corrected positions. Over correction may also be beneficial to speed the rate of correction, i.e. by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, treatment can be terminated before the teeth reach the positions defined by the final appliance or appliances. The method will usually comprise placing at least two additional appliances, often comprising placing at least ten additional appliances, sometimes placing at least twenty-five additional appliances, and occasionally placing at least forty or more additional appliances. Successive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

Often, it may be desirable to replace the appliances at a time before the "end" tooth arrangement of that treatment stage is actually achieved. It will be appreciated that as the teeth are gradually repositioned and approach the geometry defined by a particular appliance, the repositioning force on the individual teeth will diminish greatly. Thus, it may be possible to reduce the overall treatment time by replacing an earlier appliance with the successive appliance at a time when the teeth have been only partially repositioned by the earlier appliance. Thus, the FDDS can actually represent an over correction of the final tooth position. This both speeds the treatment and can offset patient relapse.

In general, the transition to the next appliance can be based on a number of factors. Most simply, the appliances can be replaced on a predetermined schedule or at a fixed time interval (i.e. number of days for each appliance) determined at the outset based on an expected or typical patient response. Alternatively, actual patient response can be taken into account, e.g. a patient can advance to the next appliance when that patient no longer perceives pressure on

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their teeth from a current appliance, i.e. the appliance they have been wearing fits easily over the patient's teeth and the patient experiences little or no pressure or discomfort on his or her teeth. In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances, i.e. reduce the total number of appliances being used below the number determined at the outset. In this way, the overall treatment time for a particular patient can be reduced.

In another aspect, methods of the present invention comprise repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. The present invention provides improvements to such methods which comprise determining at the outset of treatment geometries for at least three of the appliances which are to be worn successively by a patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement. Preferably, at least four geometries will be determined in the outset, often at least ten geometries, frequently at least twenty-five geometries, and sometimes forty or more geometries. Usually, the tooth positions defined by the cavities in each successive geometry differ from those defined by the prior geometry by no more than 2 mm, preferably no more than 1 mm, and often no more than 0.5 mm, as defined above.

In yet another aspect, methods are provided for producing a digital data set representing a final tooth arrangement. The methods comprise providing an initial data set representing an initial tooth arrangement, and presenting a visual image based on the initial data set. The visual image is then manipulated to reposition individual teeth in the visual image. A final digital data set is then produced which represents the final tooth arrangement with repositioned teeth as observed in the visual image. Conveniently, the initial digital data set may be provided by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like. Preferably, the images will be three-dimensional images and digitization may be accomplished using conventional technology. Usually, the initial digital data set is provided by producing a plaster cast of the patient's teeth (prior to treatment) by conventional techniques. The plaster cast so produced may then be scanned using laser or other scanning equipment to produce a high resolution digital representation of the plaster cast of the patient's teeth. Use of the plaster cast is preferred since it does not expose the patient to X-rays or subject the patient to the inconvenience of an MRI scan.

Once the digital data set is acquired, an image can be presented and manipulated on a suitable computer system equipped with computer-aided design software, as described in greater detail below. The image manipulation will usually comprise defining boundaries about at least some of the individual teeth, and causing the images of the teeth to be moved relative to the jaw and other teeth by manipulation of the image via the computer. The image manipulation can be done entirely subjectively, i.e. the user may simply reposition teeth in an aesthetically and/or therapeutically desired manner based on observation of the image alone. Alternatively, the computer system could be provided with rules and algorithms which assist the user in repositioning the teeth. In some instances, it will be possible to provide rules and algorithms which reposition the teeth in a fully automatic manner, i.e. without user intervention. Once the

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individual teeth have been repositioned, a final digital data set representing the desired final tooth arrangement will be generated and stored.

A preferred method for determining the final tooth arrangement is for the treating professional to define the final tooth positions, e.g. by writing a prescription. The use of prescriptions for defining the desired outcomes of orthodontic procedures is well known in the art. When a prescription or other final designation is provided, the image can then be manipulated to match the prescription. In some cases, it would be possible to provide software which could interpret the prescription in order to generate the final image and thus the digital data set representing the final tooth arrangement.

In yet another aspect, methods according to the present invention are provided for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement. Such methods comprise providing a digital data set representing an initial tooth arrangement (which may be accomplished according to any of the techniques set forth above). A digital data set representing a final tooth arrangement is also provided. Such final digital data set may be determined by the methods described previously. The plurality of successive digital data sets are then produced based on the initial digital data set and the final digital data set. Usually, the successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences. Such interpolation may be performed over as many discrete stages as may be desired, usually at least three, often at least four, more often at least ten, sometimes at least twenty-five, and occasionally forty or more. Many times, the interpolation will be linear interpolation for some or all of the positional differences. Alternatively, the interpolation may be non-linear. The positional differences will correspond to tooth movements where the maximum linear movement of any point on a tooth is 2 mm or less, usually being 1 mm or less, and often being 0.5 mm or less.

Often, the user will specify certain target intermediate tooth arrangements, referred to as "key frames," which are incorporated directly into the intermediate digital data sets. The methods of the present invention then determine successive digital data sets between the key frames in the manner described above, e.g. by linear or non-linear interpolation between the key frames. The key frames may be determined by a user, e.g. the individual manipulating a visual image at the computer used for generating the digital data sets, or alternatively may be provided by the treating professional as a prescription in the same manner as the prescription for the final tooth arrangement.

In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements. Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine

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may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of non-hardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines.

In still another aspect, methods of the present invention for fabricating a dental appliance comprise providing a digital data set representing a modified tooth arrangement for a patient. A fabrication machine is then used to produce a positive model of the modified tooth arrangement based on the digital data set. The dental appliance is then produced as a negative of the positive model. The fabrication machine may be a stereolithography or other machine as described above, and the positive model is produced by conventional pressure or vacuum molding techniques.

In a still further aspect, methods for fabricating a dental appliance according to the present invention comprise providing a first digital data set representing a modified tooth arrangement for a patient. A second digital data set is then produced from the first digital data set, where the second data set represents a negative model of the modified tooth arrangement. The fabrication machine is then controlled based on the second digital data set to produce the dental appliance. The fabrication machine will usually rely on selectively hardening a non-hardened resin to produce the appliance. The appliance typically comprises a polymeric shell having a cavity shape to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

FIG. 1B illustrates a single tooth from FIG. 1A and defines how tooth movement distances are determined.

FIG. 1C illustrates the jaw of FIG. 1A together with an incremental position adjustment appliance which has been configured according to the methods of the present invention.

FIG. 2 is a block diagram illustrating the steps of the present invention for producing a system of incremental position adjustment appliances.

FIG. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

FIG. 4 is a flow chart illustrating an eraser tool for the methods herein.

FIG. 4A illustrates the volume of space which is being erased by the program of FIG. 4.

FIG. 5 is a flow chart illustrating a program for matching high-resolution and low-resolution components in the manipulation of data sets of FIG. 3.

FIG. 6 illustrates the method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances of the present invention.

FIG. 7 illustrates alternative processes for producing a plurality of appliances according to the methods of the present invention utilizing digital data sets representing the intermediate and final appliance designs.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

According to the present invention, systems and methods are provided for incrementally moving teeth using a plural-

ity of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

Referring now to FIG. 1A, a representative jaw 100 includes sixteen teeth 102. The present invention is intended to move at least some of these teeth from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this centerline (CL), the teeth may be moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally, the tooth 20 may be rotated about the centerline, as represented by arrow 114. Thus, all possible free-form motions of the tooth can be performed. Referring now to FIG. 1B, the magnitude of any tooth movement achieved by the methods and devices of the present invention will be defined in terms of the maximum linear translation of any point P on a tooth 102. Each point P_i will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in FIG. 1A. That is, while the point will usually follow a non-linear path, there will be a linear distance 30 between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P_i may in fact undergo a true side-to-side translation as indicated by arrow d₁, while a second arbitrary point P₂ may travel along an arcuate path, resulting in a final translation d₂. Many 35 aspects of the present invention are defined in terms of the maximum permissible movement of a point P_i induced by the methods in any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point P_i on the tooth which undergoes the maximum movement for that tooth in any treatment step.

Referring now to FIG. 1C, systems according to the present invention will comprise a plurality of incremental position adjustment appliances. The appliances are intended to effect incremental repositioning of individual teeth in the jaw as described generally above. In a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. 45 The systems of the present invention, in contrast with prior apparatus and systems, will provide a plurality of such appliances intended to be worn by a patient successively in order to achieve the gradual tooth repositioning as described herein. A preferred appliance 100 will comprise a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably, but not necessarily, fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others of the teeth will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, many or most of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance. Additionally, the gums and/or the

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palette can serve as an anchor region, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

The polymeric appliance 100 of FIG. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, Tru-Tain Plastics, Rochester, Minn. 55902. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor. Specific methods for producing the appliances 100 are described hereinafter.

Referring now to FIG. 2, the overall method of the present invention for producing the incremental position adjustment appliances for subsequent use by patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the IDDS. The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. Methods for digitizing such conventional images to produce data sets useful in the present invention are well known and described in the patent and medical literature. Usually, however, the present invention will rely on first obtaining a plaster cast of the patient's teeth by well known techniques, such as those described in Gruber, *Orthodontics: Principle and Practice*, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415. After the tooth casting is obtained, it can be digitally scanned using a conventional laser scanner or other range acquisition system to produce the IDDS. The data set produced by the range acquisition system may, of course, be converted to other formats to be compatible with the software which is used for manipulating images within the data set, as described in more detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Pat. No. 5,605,459, the full disclosure of which is incorporated herein by reference.

There are a variety of range acquisition systems, generally categorized by whether the process of acquisition requires contact with the three dimensional object. A contact-type range acquisition system utilizes a probe, having multiple degrees of translational and/or rotational freedom. By recording the physical displacement of the probe as it is drawn across the sample surface, a computer-readable representation of the sample object is made. A non-contact-type range acquisition device can be either a reflective-type or transmissive-type system. There are a variety of reflective systems in use. Some of these reflective systems utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Those non-contact-type systems working by reflected optical energy further contain special instrumentation configured to permit certain measuring techniques to be performed (e.g., imaging radar, triangulation and interferometry).

A preferred range acquisition system is an optical, reflective, non-contact-type scanner. Non-contact-type scanners are preferred because they are inherently nondestructive (i.e., do not damage the sample object), are generally characterized by a higher capture resolution and scan a sample in a relatively short period of time. One such scanner is the Cyberware Model 15 manufactured by Cyberware, Inc., Monterey, Calif.

Either non-contact-type or contact-type scanners may also include a color camera, that when synchronized with the scanning capabilities, provides a means for capturing, in digital format, a color representation of the sample object. The importance of this further ability to capture not just the shape of the sample object but also its color is discussed below.

The methods of the present invention will rely on manipulating the IDDS at a computer or workstation having at least one processor and memory having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present invention.

Referring again to FIG. 2, after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDS's, as described in more detail below.

FIG. 3 illustrates a representative technique for manipulating the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner will be in a high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data set representing the IDDS at a lower resolution will be created. The user will manipulate the lower resolution images while the computer will update the high resolution data set as necessary. The user can also view/manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS will also be converted into a quad edge data structure if not already present in that form. A quad edge data structure is a standard topological data structure defined in *Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams*, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

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As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and other oral tissue, the user will usually delete structure which is unnecessary for image manipulation and/or final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI. Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and/or which teeth will be extracted. Shaving allows the patient to maintain their teeth when only a small amount of space is needed. Typically, extraction and shaving, of course, will be utilized in the treatment planning only when the actual patient teeth are to be extracted and/or shaved prior to initiating repositioning according to the methods of the present invention.

Removing unwanted and/or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and instructs the software to erase the unwanted section, all triangles within the box set by the user will be removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of the box. The holes created in the model at the faces of the box are re-triangulated and closed using the newly created vertices.

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the tooth or other component images independent of remaining portions of the model. The saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes. A set of lines connects the two curves and shows the user the general cutting path. The user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However, the user may want to make a thicker cut, for example, when shaving down surrounding teeth, as described above. Graphically, the cut appears as the curve bounded by half the thickness of the cut on each side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear approximation of the Saw Tool's curve path. The user chooses the number of erasers, which determines the sophistication of the curve created—the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline

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curves. Once a saw cut has been completely specified the user applies the cut to the model. The cut is performed as a sequence of erasing. A preferred algorithm is set forth in FIG. 4. FIG. 4A shows a single erasing iteration of the cut as described in the algorithm.

A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

After the user has completed all desired cutting operations with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components. The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. The algorithm is described in FIG. 5.

After the teeth and other components have been placed or removed so that the final tooth arrangement has been produced, it is necessary to generate a treatment plan, as illustrated in FIG. 6. The treatment plan will ultimately produce the series of INTDDS's and PDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes. For example, it may be desirable to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit the tooth to be manipulated in a manner that requires the anchor, e.g. lifted relative to the jaw.

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous structure in order to permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances. The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path as well as the teeth and other components.

In the manufacturing process, which relies on generation of positive models to produce the repositioning appliance,

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adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and the appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been added to the mold. When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which engages an anchor placed on the teeth in order to move the tooth in directions which could not otherwise be accomplished.

In addition to such wax patches, an individual component, usually a tooth, can be scaled to a smaller or larger size which will result in a manufactured appliance having a tighter or looser fit, respectively.

Treatment planning is extremely flexible in defining the movement of teeth and other components. The user may change the number of treatment stages, as well as individually control the path and speed of components.

Number of Treatment Stages: The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

Key frames: The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). Unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the initial position, all key frame positions, and the target position). For example, if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position. If the user specifies two key frames for that component, it will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, possibly in yet a different direction, linearly to the target position.

The user can also specify non-linear interpolation between the key frames. A spline curve is used to specify the interpolating function in a conventional manner.

These operations may be done independently to each component, so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between stages 3 and 8, while another moves linearly from stage 1 to 5, and then changes direction suddenly and slows down along a linear path to stage 10. This flexibility allows a great deal of freedom in planning a patient's treatment.

Lastly, the software may incorporate and the user may at any point use a "movie" feature to automatically animate the movement from initial to target states. This is helpful for visualizing overall component movement throughout the treatment process.

Above it was described that the preferred user interface for component identification is a three dimensional interactive GUI. A three-dimensional GUI is also preferred for component manipulation. Such an interface provides the

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treating professional or user with instant and visual interaction with the digital model components. It is preferred over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular segment. In other words, a GUI adapted for manipulation is preferred over an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots. Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

The software also allows for adding annotations to the datasets which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e. it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in FIG. 7. Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the trademark BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

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After production, the plurality of appliances which comprise the system of the present invention are preferably supplied to the treating professional all at one time. The appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for producing a digital data set representing a final tooth arrangement, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;
presenting a visual image based on the initial data set;
manipulating the visual image to reposition individual teeth in the visual image;
producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and
producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

2. A method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

3. A method as in claim 2, wherein the manipulating step comprises:

defining boundaries about at least some of the individual teeth; and
moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

4. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

providing a computer system having at least one processor and memory;
providing to the computer system an initial digital data set representing an initial tooth arrangement;
providing to the computer system a final digital data set representing a final tooth arrangement;
producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

5. A method as in claim 4, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

6. A method as in claim 4, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and
moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

7. A method as in claim 4, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

8. A method as in claim 7, wherein the interpolating step comprises linear interpolation.

9. A method as in claim 7, wherein the interpolating step comprises non-linear interpolation.

10. A method as in claim 7, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

11. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;
providing a final digital data set representing a final tooth arrangement;
producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and
fabricating appliances based on at least some of the produced digital data sets.

12. A method as in claim 11, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

13. A method as in claim 11, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth; and
moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the final data set.

14. A method as in claim 11, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

15. A method as in claim 14, wherein the interpolating step comprises linear interpolation.

16. A method as in claim 14, wherein the interpolating step comprises non-linear interpolation.

17. A method as in claim 14, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

18. A method as in claim 11, wherein the fabricating step comprises:

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and
producing the dental appliance as a negative of the positive model.

19. A method as in claim 18, wherein the controlling step comprises:

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providing a volume of non-hardened polymeric resin; and scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

20. A method as in claim 18, wherein the producing step comprises modeling the appliance over the positive model.

21. A method for fabricating a dental appliance, said method comprising:

providing a digital data set representing a modified tooth arrangement for a patient;

controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and

producing the dental appliance as a negative of the positive model.

22. A method as in claim 21, wherein the controlling step comprises:

providing a volume of non-hardened polymeric resin;

scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

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23. A method as in claim 21, wherein the producing step comprises molding the appliance over the positive model.

24. A method for fabricating a dental appliance, said method comprising:

providing a first digital data set representing a modified tooth arrangement for a patient;

producing a second digital data set from the first data set, wherein the second data set represents a negative model of the modified tooth arrangement; and

controlling a fabrication machine based on the second digital data set to produce the dental appliance.

25. A method as in claim 24, wherein the controlling step comprises selectively hardening a non-hardened resin to produce the appliance and separating the appliance from the remaining liquid resin.

26. A method as in claim 24, wherein the appliance comprises a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

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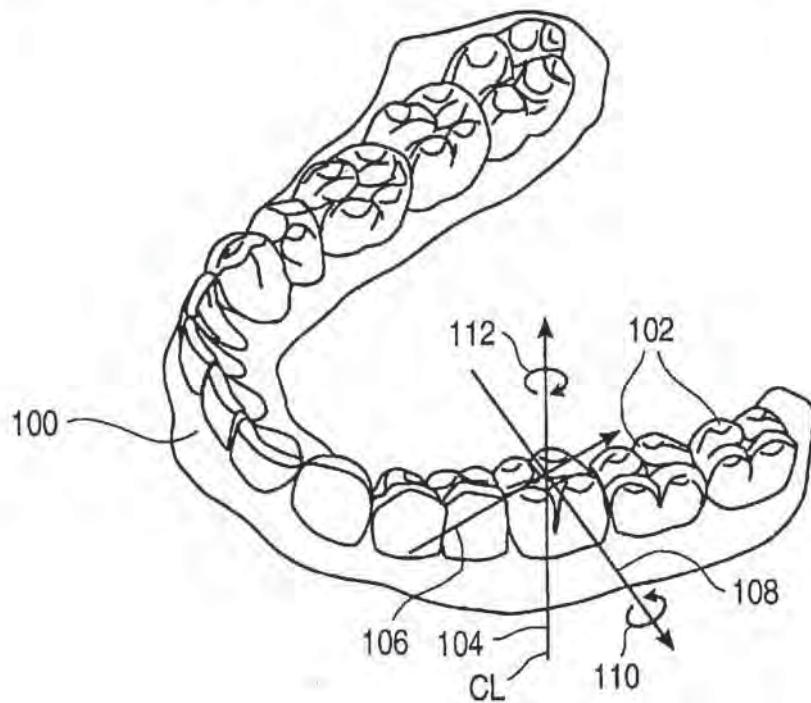


FIG. 1A

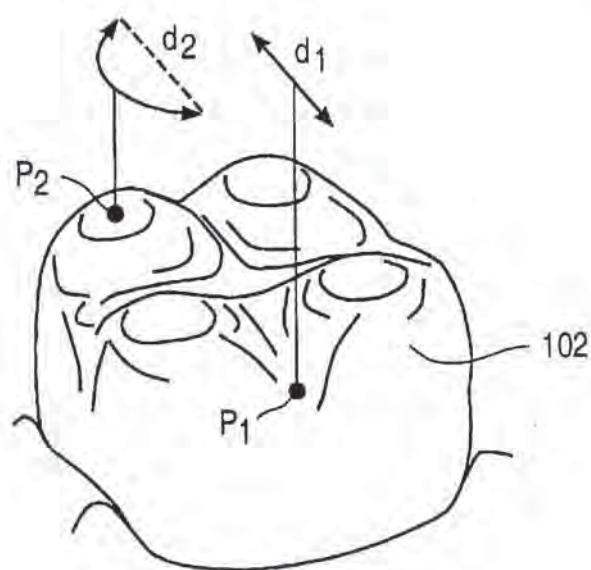


FIG. 1B

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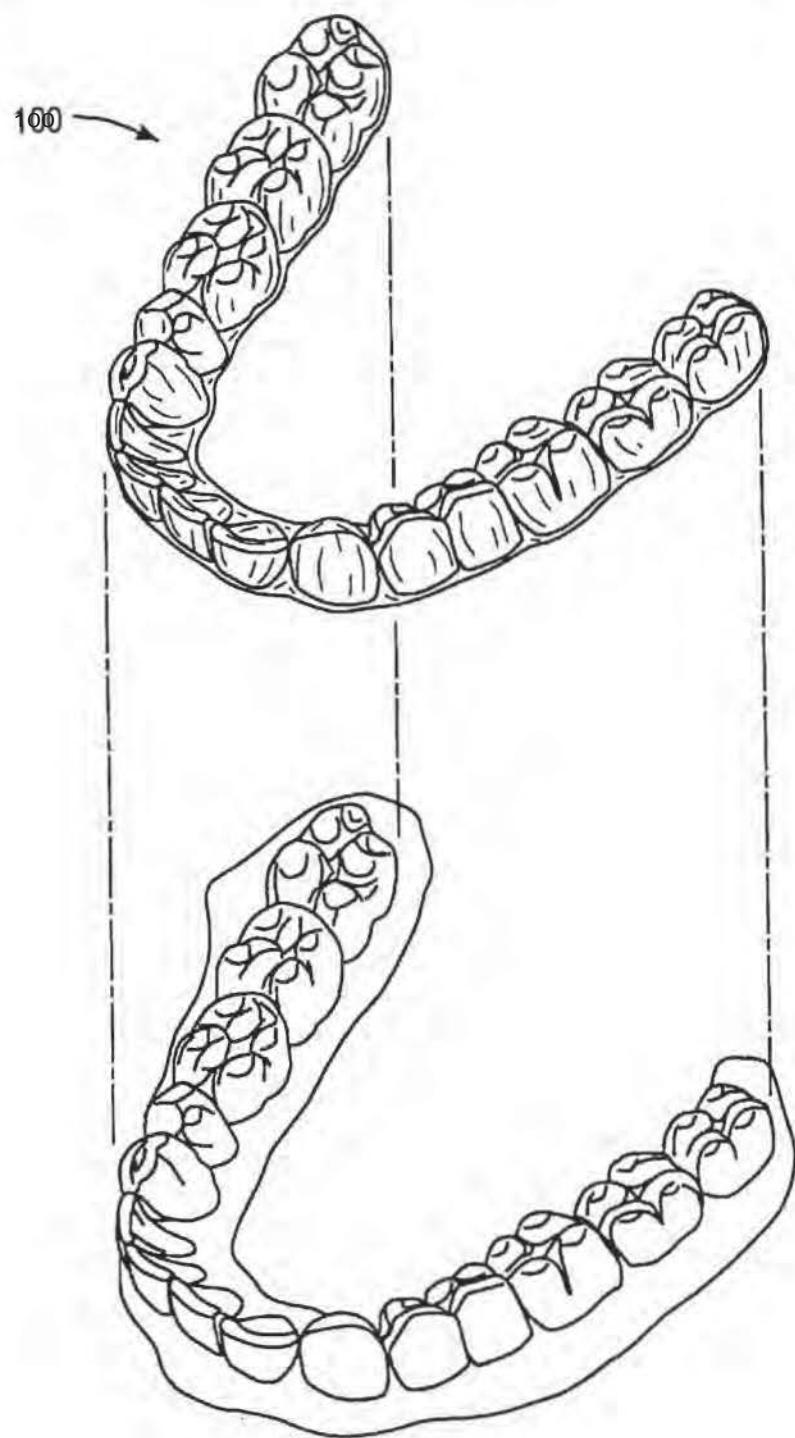


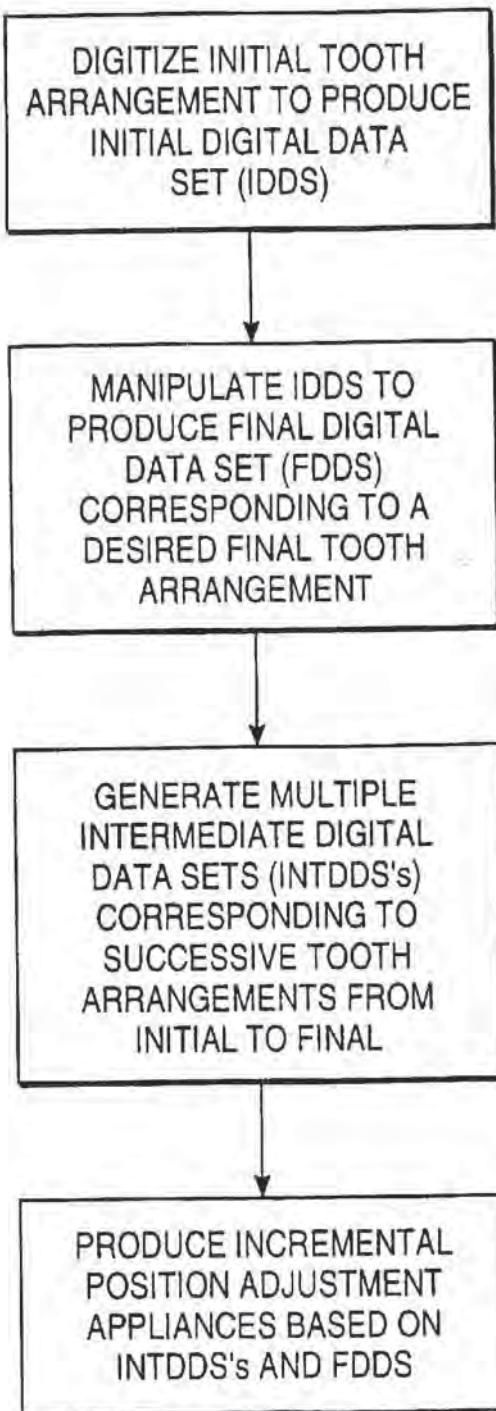
FIG. 10

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FIG. 3CROSS-REFERENCE
FIG. 6**FIG. 2****A2935**

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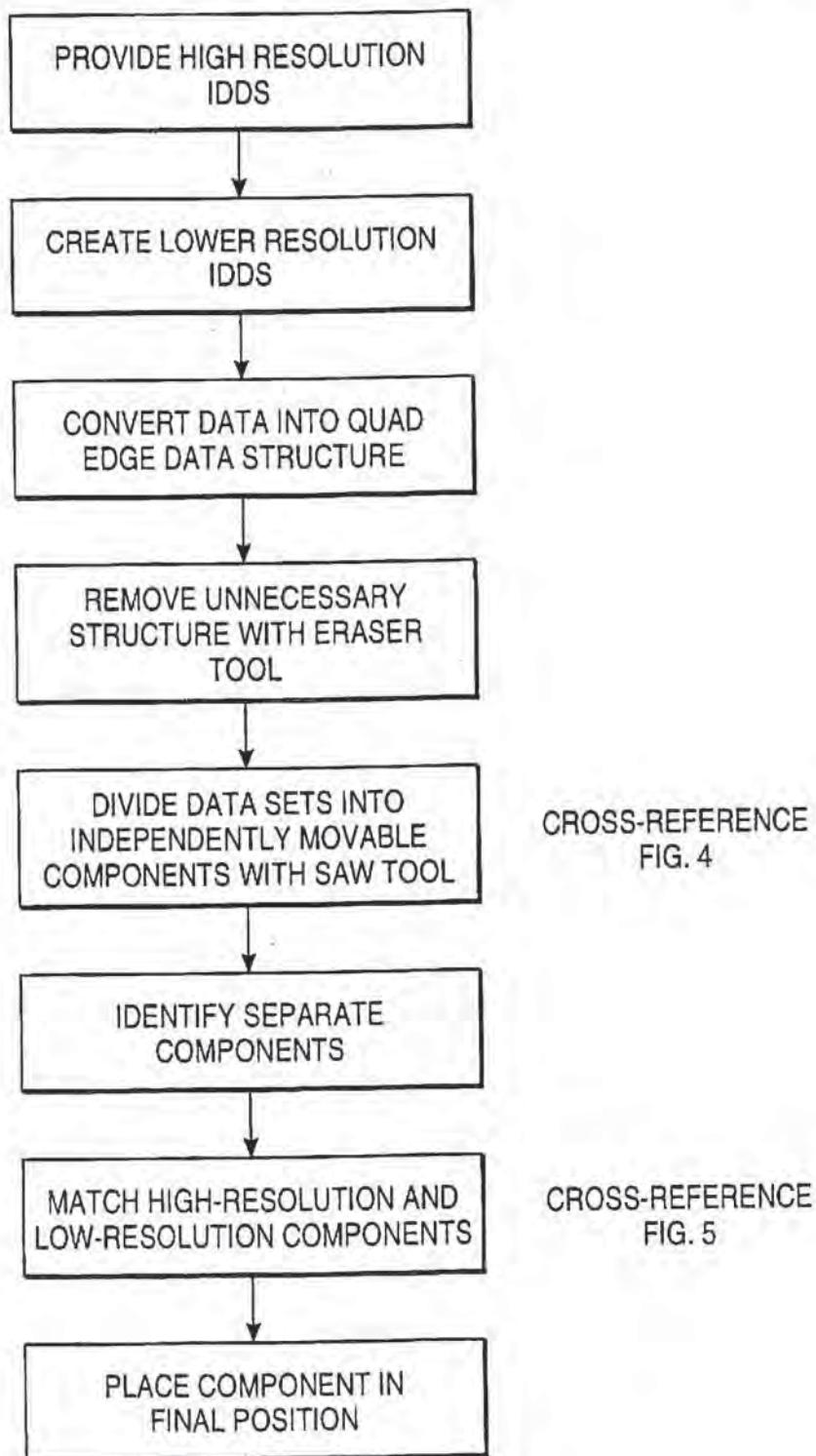


FIG. 3

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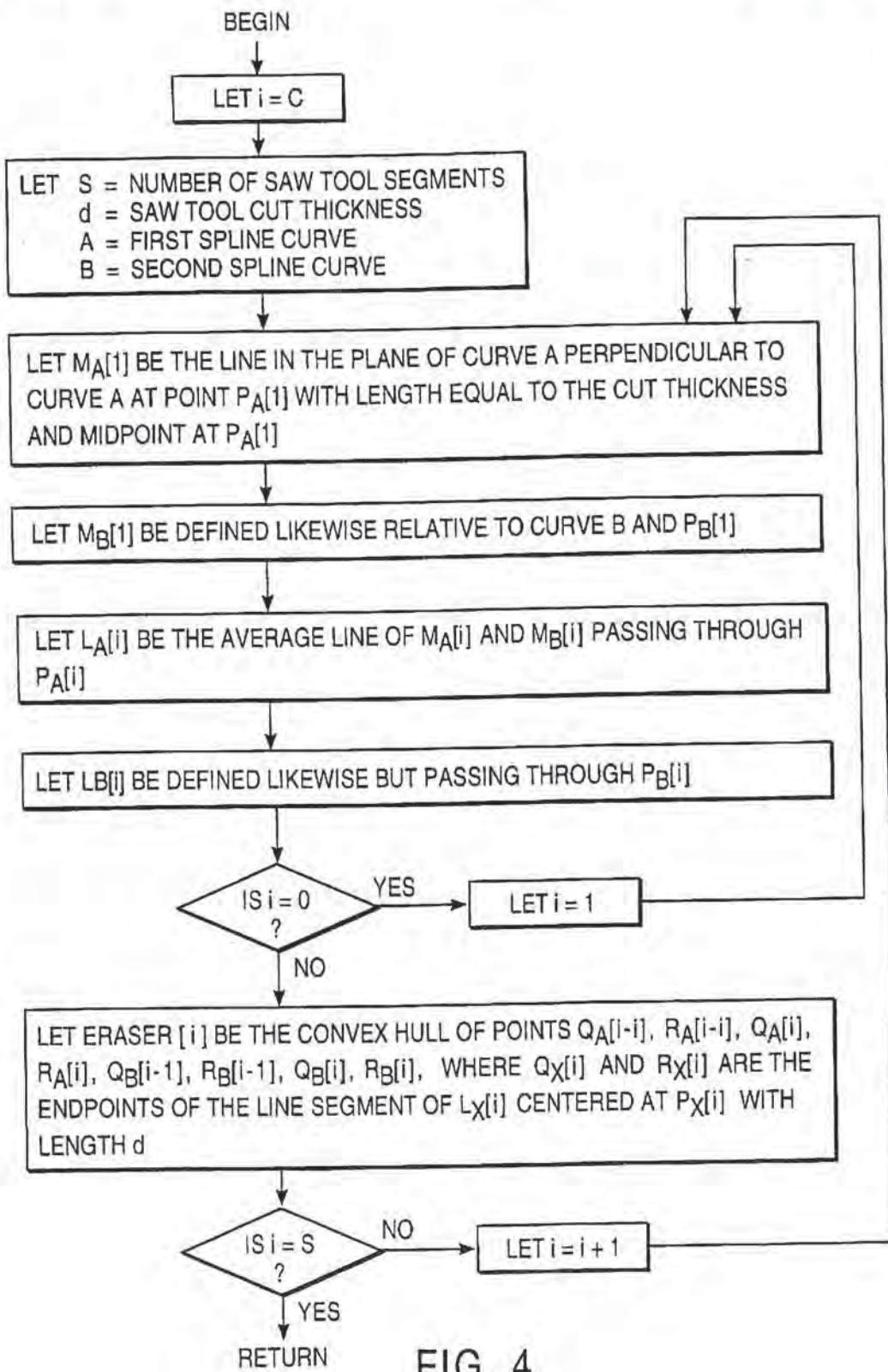


FIG. 4

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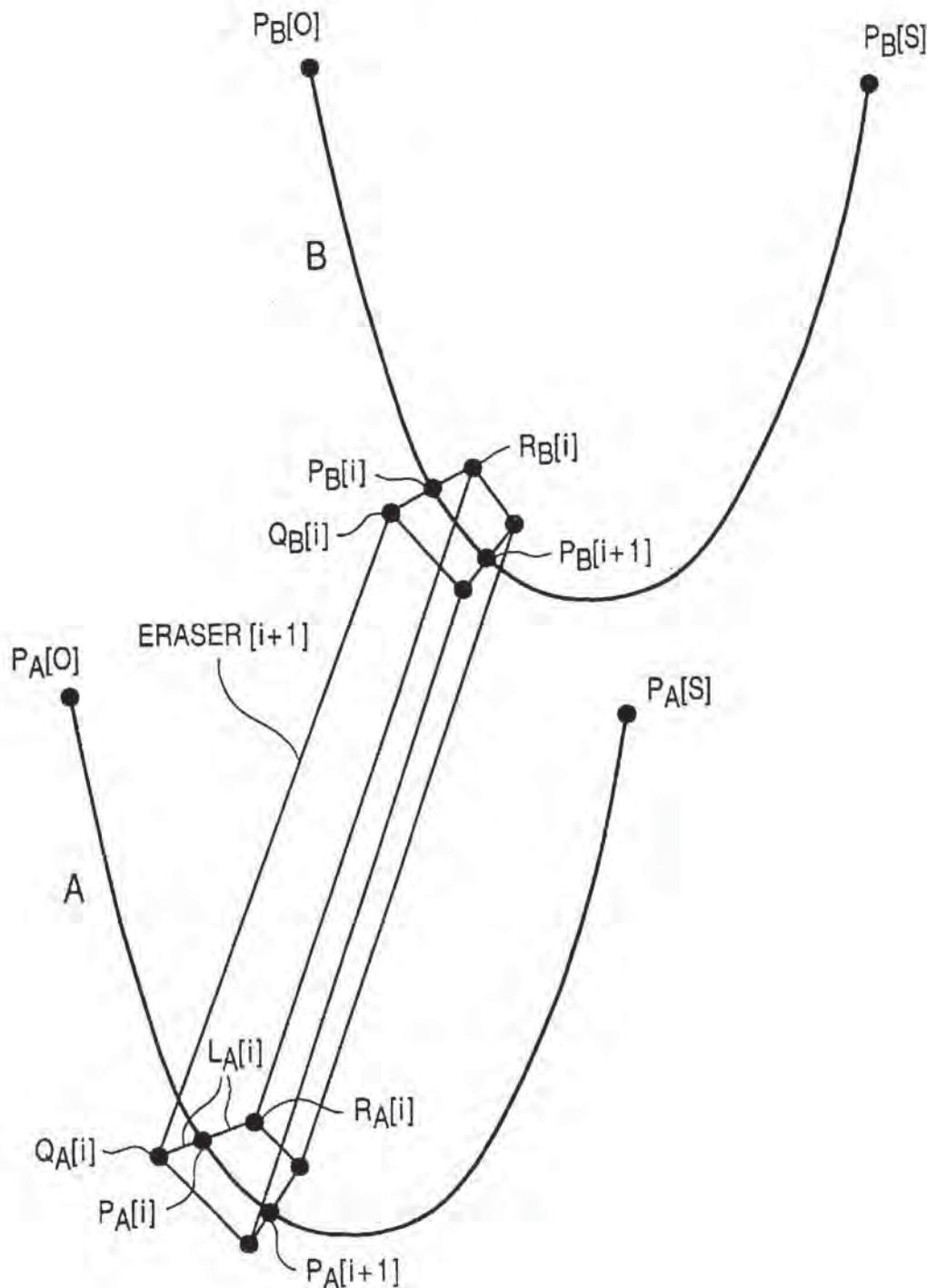


FIG. 4A

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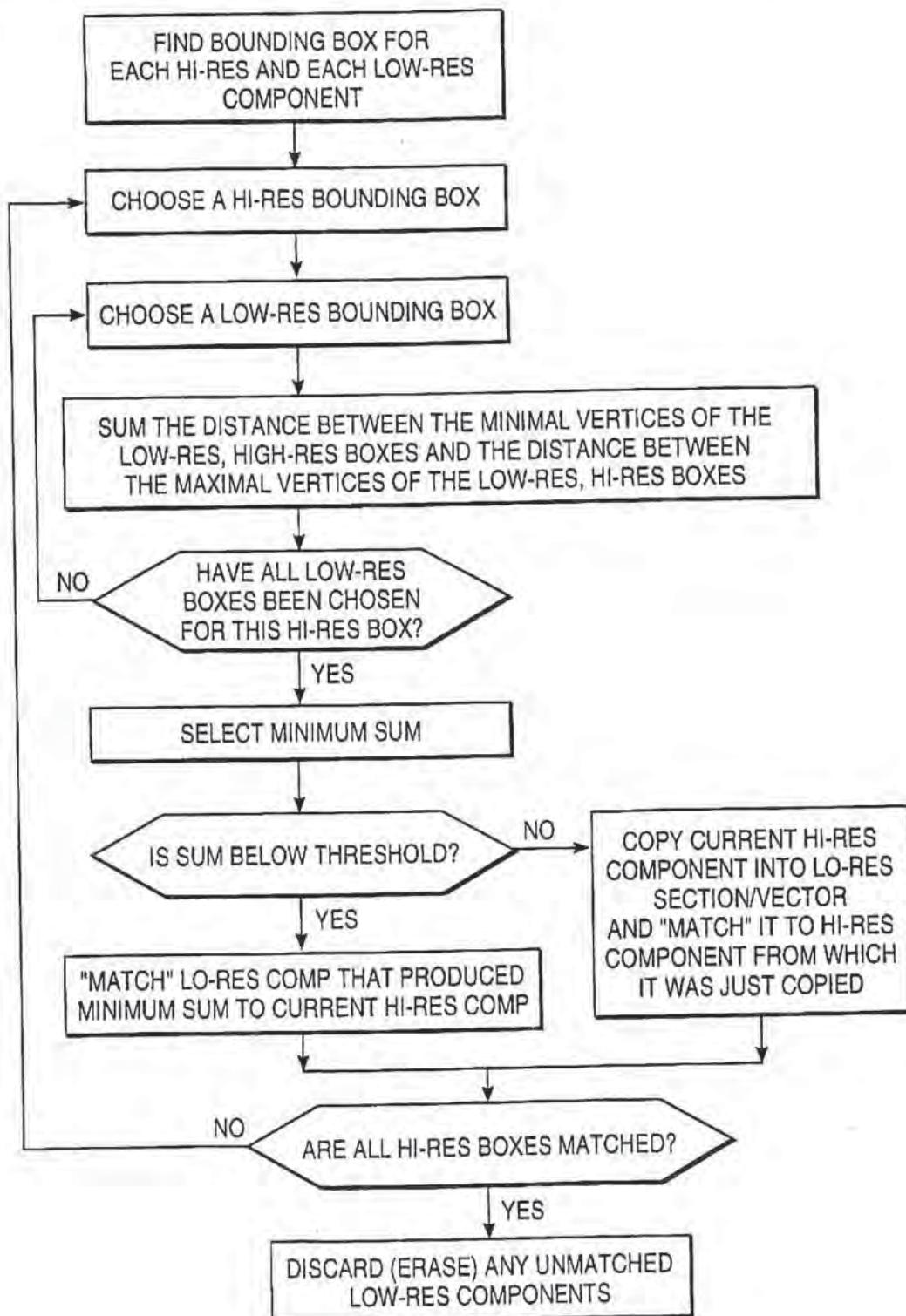


FIG. 5

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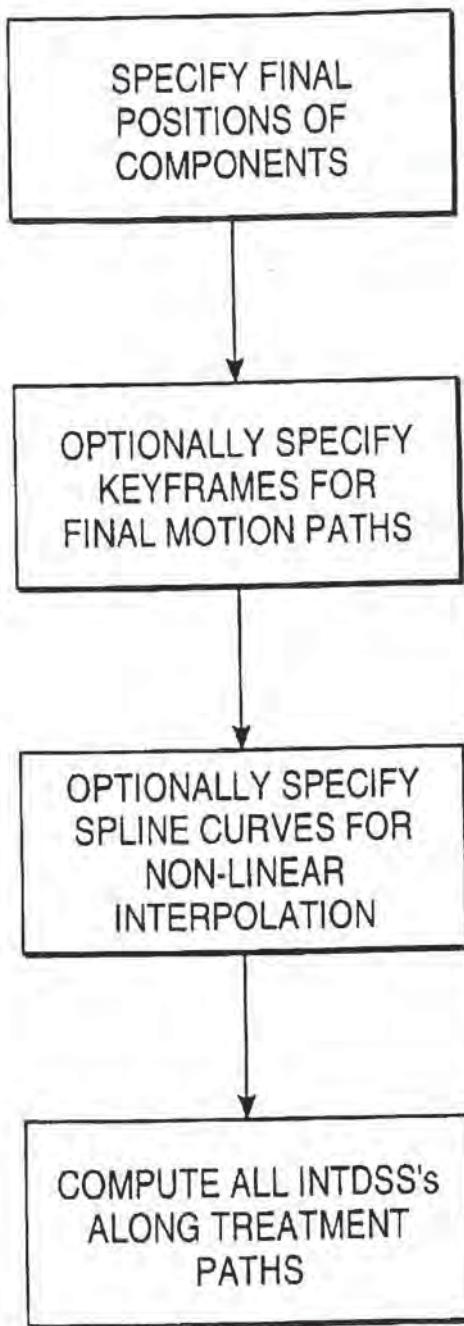


FIG. 6

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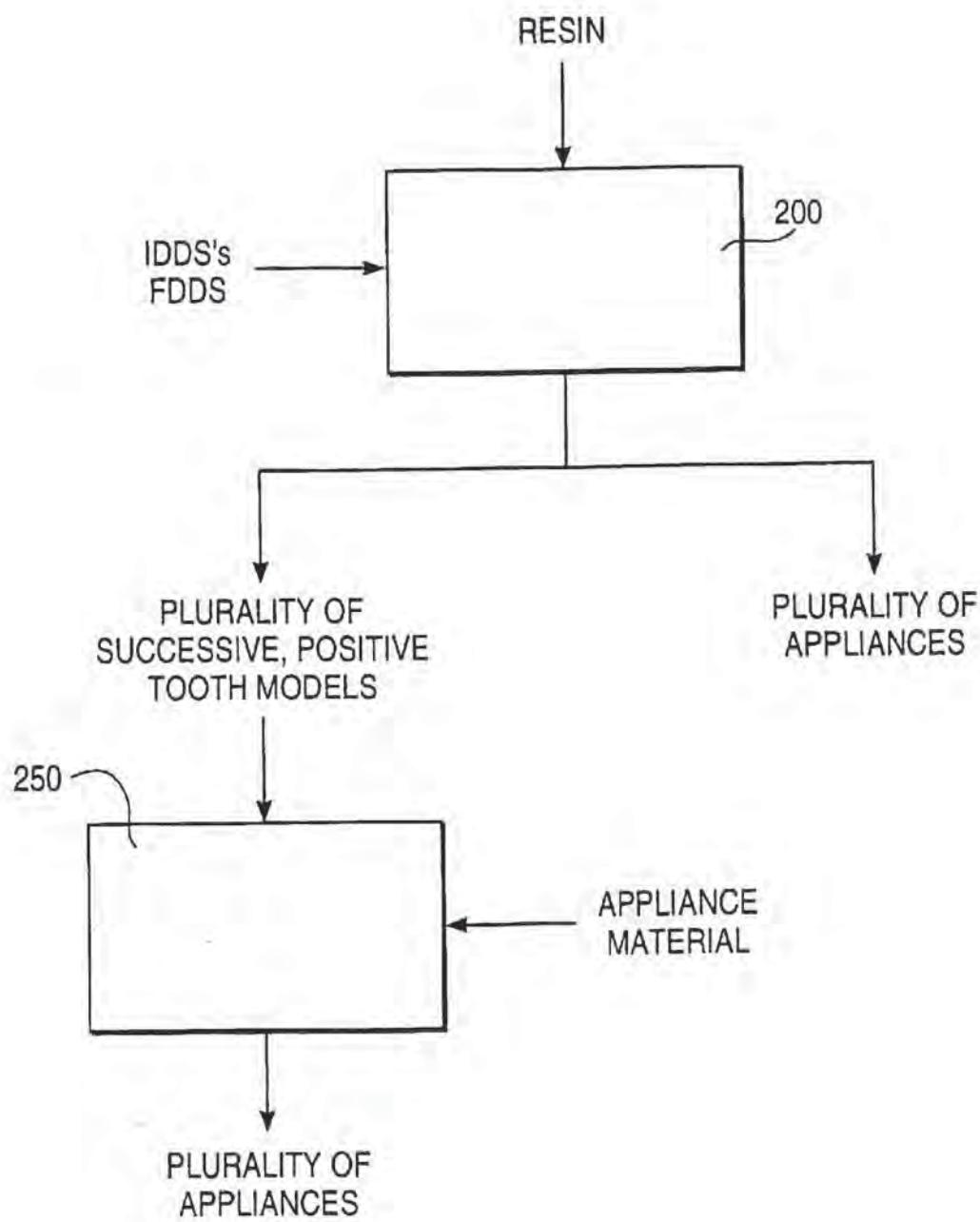


FIG. 7

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(12) EX PARTE REEXAMINATION CERTIFICATE (6097th)
United States Patent
Chishti et al.

(10) Number: **US 6,217,325 C1**
 (45) Certificate Issued: *Jan. 15, 2008

(54) **METHOD AND SYSTEM FOR
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(73) Assignee: Align Technology, Inc., Redwood City, CA (US)

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Filed:	Apr. 23, 1999

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- (62) Division of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.
 (60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) **Int. Cl.**

<i>A61C 7/00</i>	(2006.01)
<i>A61C 13/00</i>	(2006.01)
<i>A61C 9/00</i>	(2006.01)
<i>A61C 3/00</i>	(2006.01)

- (52) U.S. Cl. 433/24; 433/213; 433/215
 (58) Field of Classification Search 433/24,
433/213, 215

See application file for complete search history.

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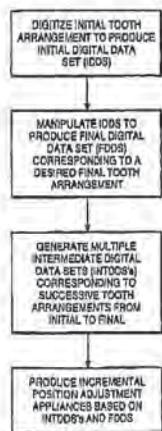
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(57) **ABSTRACT**

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.



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**EX PARTE
REEXAMINATION CERTIFICATE
ISSUED UNDER 35 U.S.C. 307**

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 11-17 and 24-26 is confirmed.

Claims 4-10 are cancelled.

Claims 1 and 18-21 are determined to be patentable is amended.

Claims 2, 3, 22 and 23, dependent on an amended claim, are determined to be patentable.

New claims 27-39 are added and determined to be patentable.

1. A method for *facilitating a tooth repositioning dental treatment, including producing a plurality of digital [set] sets representing a [final] plurality of tooth [arrangement] arrangements*, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;

presenting a visual image based on the initial data set; manipulating the visual image to reposition individual teeth in the visual image;

producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; [and]

producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating a plurality of successive tooth repositioning appliances, at least some of which are related to at least some of the produced digital data sets.

18. A method as in claim 11, wherein the fabricating step comprises:

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the dental [appliance] appliances as [a negative] negatives of the positive [model] models.

19. A method as in claim 18, wherein the controlling step comprises, for each of the successive positive models:

providing a volume of non-hardened polymeric resin; and scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

20. A method as in claim 18, wherein the producing step comprises modeling the [appliance] appliances over the positive [model] models.

21. A method for fabricating a polymeric shell dental appliance for moving a patient's teeth, said method comprising:

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providing a digital data set representing a modified tooth arrangement for a patient, wherein the modified tooth arrangement comprises a repositioned tooth arrangement for a plurality of the patient's teeth;

controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement; and

producing the polymeric shell dental appliance as a negative of the positive model, wherein the polymeric shell appliance covers a plurality of teeth in an upper or lower jaw of the patient, and wherein the polymeric shell appliance is configured to move at least some of the patient's teeth substantially to the modified tooth arrangement.

27. A method as in claim 1, wherein fabricating the tooth repositioning appliances comprises fabricating polymeric shell appliances.

28. A method as in claim 11, wherein fabricating the appliances comprises fabricating a series of successive appliances.

29. A method as in claim 28, wherein fabricating the appliances comprises fabricating polymeric shell appliances.

30. A method as in claim 21, wherein the digital data set represents substantially accurate shapes of the patient's actual teeth in the modified tooth arrangement.

31. A method for facilitating a tooth repositioning dental treatment of a patient by use of a series of successive tooth positioning appliances, including producing a plurality of digital data sets representing a plurality of tooth arrangements and providing a plurality of the digital data sets to a fabrication operation for facilitating the treatment, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;

presenting a visual image based on the initial data set; manipulating the visual image to reposition individual teeth in the visual image;

producing a final digital data set representing the final tooth arrangement with repositioned teeth as observed in the image;

producing a plurality of intermediate digital data sets representing a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

providing a plurality of the produced intermediate digital data sets to a fabrication operation to facilitate the tooth repositioning dental treatment of the patient with a series of successive tooth repositioning appliances.

32. A method as in claim 31, wherein the produced digital data sets represent substantially accurate shapes of the patient's actual teeth.

33. A method as in claim 31, further comprising fabricating a plurality of successive tooth repositioning appliances based on at least a plurality of said produced digital data sets provided to the fabrication operation.

34. A method as in claim 33, wherein fabricating the successive tooth repositioning appliances comprises fabricating polymeric shell appliances.

35. A method for fabricating a plurality of successive dental incremental position adjustment appliances, said method comprising:

providing an initial digital data set representing an initial tooth arrangement;

providing a final digital data set representing the final tooth arrangement;

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producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement;

controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the successive dental appliances as negatives 10 of the positive models.

36. A method as in claim 35, wherein the controlling step comprises, for each of the successive positive models:

providing a volume of non-hardened polymeric resin; and 15 scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

37. A method as in claim 35, wherein the producing step comprises modeling the appliances over the positive models.

38. A method for fabricating a plurality of successive, 20 polymeric shell, dental incremental position adjustment appliances for repositioning at least some of a patient's teeth, said method comprising:

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providing an initial digital data set representing substantially accurate shapes of the patient's actual teeth in an initial tooth arrangement;

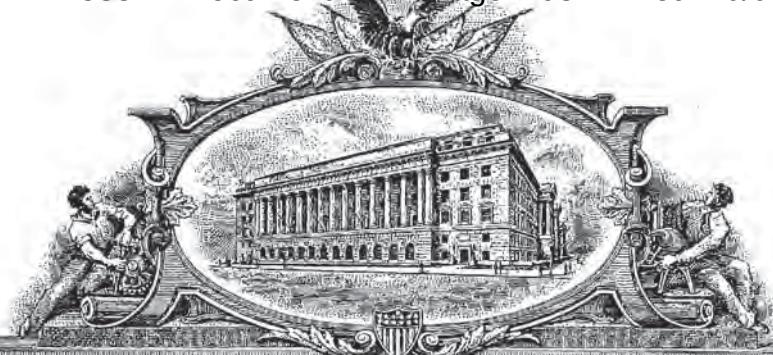
providing a final digital data set representing substantially accurate shapes of the patient's actual teeth in a final tooth arrangement;

producing a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of digital data sets represents substantially accurate shapes of the patient's actual teeth in a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; and

fabricating a plurality of successive, polymeric shell, dental incremental position adjustment appliances based on at least some of the produced digital data sets.

39. A method as in claim 38, wherein the appliances are fabricated based on individual ones of at least a corresponding plurality of the produced digital data sets.

* * * * *



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ISSUE DATE: October 29, 2002**

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Certifying Officer





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(12) **United States Patent**
Chishti et al.

(10) Patent No.: US 6,471,511 B1
(45) Date of Patent: *Oct. 29, 2002

(54) **DEFINING TOOTH-MOVING APPLIANCES COMPUTATIONALLY**

(75) Inventors: Muhammad Chishti, Menlo Park, CA (US); Elena I. Pavlovskaya, San Francisco, CA (US); Gregory P. Bala, San Jose, CA (US); Brian Freyburger, San Francisco, CA (US)

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: Oct. 8, 1998

Related U.S. Application Data

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(60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) Int. Cl.⁷ A61C 3/00

(52) U.S. Cl. 433/24; 433/6

(58) Field of Search 433/24, 6

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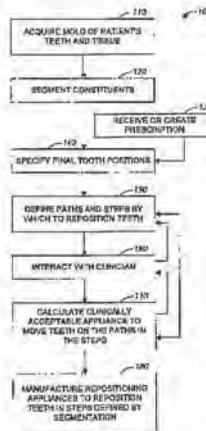
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Primary Examiner—John J. Wilson*(74) Attorney, Agent, or Firm*—Townsend and Townsend and Crew LLP; Bao Tran**(57) ABSTRACT**

Methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate sub-steps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints. The appliances can be braces, polymeric shells, or other forms of orthodontic appliance. Implementations can include comparing the actual effect of the appliances with an intended effect of the appliances; and identifying an appliance as an unsatisfactory appliance if the actual effect of the appliance is more than a threshold different from the intended effect of the appliance and modifying a model of the unsatisfactory appliance according to the results of the comparison. The model and resulting appliance can be modified by modifying the shape of the unsatisfactory appliance, by adding a dimple, by adding material to cause an overcorrection of tooth position, by adding a rim of material along a gumline to increase stiffness, by removing material to reduce stiffness, or by redefining the shape to be a shape defined by the complement of the difference between the intended effect and the actual effect of the unsatisfactory appliance.

33 Claims, 7 Drawing Sheets

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DEFINING TOOTH-MOVING APPLIANCES COMPUTATIONALLY

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of U.S. patent application Ser. No. 08/947,080 filed on Oct. 8, 1997, now U.S. Pat. No. 5,858,851 which claims the benefit of provisional application No. 60/050,342 filed on Jun. 20, 1997, the full disclosures of which are incorporated herein by reference.

The present application is related to of PCT/US98/12861 filed Jun. 18, 1998 and to commonly-owned U.S. patent application Ser. No. 09/169,276, titled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance" now abandoned, and Ser. No. 09/169,036, titled "System and Method for Positioning Teeth" filed on even date herewith, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to computational orthodontics.

In orthodontic treatment, a patient's teeth are moved from an initial to a final position using any of a variety of appliances. An appliance exerts force on the teeth by which one or more of them are moved or held in place, as appropriate to the stage of treatment.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for defining appliance configurations at the steps of a process of repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The invention can operate to define how repositioning is accomplished by a series of appliances or by a series of adjustments to appliances configured to reposition individual teeth incrementally. The invention can be applied advantageously to specify a series of appliances formed as polymeric shells having the tooth-receiving cavities, that is, shells of the kind described in the above-mentioned U.S. patent application Ser. No. 09/169,276.

A patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by making a series of incremental position adjustments using appliances specified in accordance with the invention. In one implementation, the invention is used to specify shapes for the above-mentioned polymeric shell appliances. The first appliance of a series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. The appliance is intended to be worn until the first intermediate arrangement is approached or achieved, and then one or more additional (intermediate) appliances are successively placed on the teeth. The final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to a desired final tooth arrangement.

The invention specifies the appliances so that they apply an acceptable level of force, cause discomfort only within acceptable bounds, and achieve the desired increment of tooth repositioning in an acceptable period of time. The invention can be implemented to interact with other parts of a computational orthodontic system, and in particular to interact with a path definition module that calculates the paths taken by teeth as they are repositioned during treatment.

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In general, in one aspect, the invention provides methods and corresponding apparatus for segmenting an orthodontic treatment path into clinically appropriate substeps for repositioning the teeth of a patient. The methods include providing a digital finite element model of the shape and material of each of a sequence of appliances to be applied to a patient; providing a digital finite element model of the teeth and related mouth tissue of the patient; computing the actual effect of the appliances on the teeth by analyzing the finite elements models computationally; and evaluating the effect against clinical constraints. Advantageous implementations can include one or more of the following features. The appliances can be braces, including brackets and archwires, polymeric shells, including shells manufactured by stereo lithography, retainers, or other forms of orthodontic appliance. Implementations can include comparing the actual effect of the appliances with an intended effect of the appliances; and identifying an appliance as an unsatisfactory appliance if the actual effect of the appliance is more than a threshold different from the intended effect of the appliance and modifying a model of the unsatisfactory appliance according to the results of the comparison. The model and resulting appliance can be modified by modifying the shape of the unsatisfactory appliance, by adding a dimple, by adding material to cause an overcorrection of tooth position, by adding a ridge of material to increase stiffness, by adding a rim of material along a gumline to increase stiffness, by removing material to reduce stiffness, or by redefining the shape to be a shape defined by the complement of the difference between the intended effect and the actual effect of the unsatisfactory appliance. The clinical constraints can include a maximum rate of displacement of a tooth, a maximum force on a tooth, and a desired end position of a tooth. The maximum force can be a linear force or a torsional force. The maximum rate of displacement can be a linear or angular rate of displacement. The apparatus of the invention can be implemented as a system, or it can be implemented as a computer program product, tangibly stored on a computer-readable medium, having instructions operable to cause a computer to perform the steps of the method of the invention.

Among the advantages of the invention are one or more of the following. Appliances specified in accordance with the invention apply no more than orthodontically acceptable levels of force, cause no more than an acceptable amount of patient discomfort, and achieve the desired increment of tooth repositioning in an acceptable period of time. The invention can be used to augment a computational or manual process for defining tooth paths in orthodontic treatment by confirming that proposed paths can be achieved by the appliance under consideration and within user-selectable constraints of good orthodontic practice. Use of the invention to design aligners allows the designer (human or automated) to finely tune the performance of the aligners with respect to particular constraints. Also, more precise orthodontic control over the effect of the aligners can be achieved and their behavior can be better predicted than would otherwise be the case. In addition, computationally defining the aligner geometry facilitates direct aligner manufacturing under numerical control.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features and advantages of the invention will become apparent from the description, the drawings, and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flowchart of a process of specifying a course of treatment including a subprocess for calculating aligner shapes in accordance with the invention.

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FIG. 2 is a flowchart of a process for calculating aligner shapes.

FIG. 3 is a flowchart of a subprocess for creating finite element models.

FIG. 4 is a flowchart of a subprocess for computing aligner changes.

FIG. 5A is a flowchart of a subprocess for calculating changes in aligner shape.

FIG. 5B is a flowchart of a subprocess for calculating changes in aligner shape.

FIG. 5C is a flowchart of a subprocess for calculating changes in aligner shape.

FIG. 5D is a schematic illustrating the operation of the subprocess of FIG. 5B.

FIG. 6 is a flowchart of a process for computing shapes for sets of aligners.

Like reference numbers and designations in the various drawings indicate like elements.

DETAILED DESCRIPTION

In the present invention, systems and methods are provided for defining appliance configurations or changes to appliance configurations for incrementally moving teeth. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

FIG. 1 illustrates the general flow of an exemplary process 100 for defining and generating repositioning appliances for orthodontic treatment of a patient. The process 100 includes the methods, and is suitable for the apparatus, of the present invention, as will be described. The computational steps of the process are advantageously implemented as computer program modules for execution on one or more conventional digital computers.

As an initial step, a mold or a scan of patient's teeth or mouth tissue is acquired (110). This step generally involves taking casts of the patient's teeth and gums, and may also involve taking wax bites, direct contact scanning, x-ray imaging, tomographic imaging, sonographic imaging, and other techniques for obtaining information about the position and structure of the teeth, jaws, gums and other orthodontically relevant tissue. From the data so obtained, a digital data set is derived that represents the initial (that is, pretreatment) arrangement of the patient's teeth and other tissues.

The initial digital data set, which may include both raw data from scanning operations and data representing surface models derived from the raw data, is processed to segment the tissue constituents from each other (step 120). In particular, in this step, data structures that digitally represent individual tooth crowns are produced. Advantageously, digital models of entire teeth are produced, including measured or extrapolated hidden surfaces and root structures.

The desired final position of the teeth—that is, the desired and intended end result of orthodontic treatment—can be received from a clinician in the form of a prescription, can be calculated from basic orthodontic principles, or can be extrapolated computationally from a clinical prescription (step 130). With a specification of the desired final positions of the teeth and a digital representation of the teeth themselves, the final position and surface geometry of each tooth can be specified (step 140) to form a complete model

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of the teeth at the desired end of treatment. Generally, in this step, the position of every tooth is specified. The result of this step is a set of digital data structures that represents an orthodontically correct repositioning of the modeled teeth relative to presumed-stable tissue. The teeth and tissue are both represented as digital data.

Having both a beginning position and a final position for each tooth, the process next defines a tooth path for the motion of each tooth. The tooth paths are optimized in the aggregate so that the teeth are moved in the quickest fashion with the least amount of round-tripping to bring the teeth from their initial positions to their desired final positions. (Round-tripping is any motion of a tooth in any direction other than directly toward the desired final position. Round-tripping is sometimes necessary to allow teeth to move past each other.) The tooth paths are segmented. The segments are calculated so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation. In this way, the end points of each path segment can constitute a clinically viable repositioning, and the aggregate of segment end points constitute a clinically viable sequence of tooth positions, so that moving from one point to the next in the sequence does not result in a collision of teeth.

The threshold limits of linear and rotational translation are initialized, in one implementation, with default values based on the nature of the appliance to be used. More individually tailored limit values can be calculated using patient-specific data. The limit values can also be updated based on the result of an appliance-calculation (step 170, described later), which may determine that at one or more points along one or more tooth paths, the forces that can be generated by the appliance on the then-existing configuration of teeth and tissue is incapable of effecting the repositioning that is represented by one or more tooth path segments. With this information, the subprocess defining segmented paths (step 150) can recalculate the paths or the affected subpaths.

At various stages of the process, and in particular after the segmented paths have been defined, the process can, and generally will, interact with a clinician responsible for the treatment of the patient (step 160). Clinician interaction can be implemented using a client process programmed to receive tooth positions and models, as well as path information from a server computer or process in which other steps of process 100 are implemented. The client process is advantageously programmed to allow the clinician to display an animation of the positions and paths and to allow the clinician to reset the final positions of one or more of the teeth and to specify constraints to be applied to the segmented paths. If the clinician makes any such changes, the subprocess of defining segmented paths (step 150) is performed again.

The segmented tooth paths and associated tooth position data are used to calculate clinically acceptable appliance configurations (or successive changes in appliance configuration) that will move the teeth on the defined treatment path in the steps specified by the path segments (step 170). Each appliance configuration represents a step along the treatment path for the patient. The steps are defined and calculated so that each discrete position can follow by straight-line tooth movement or simple rotation from the tooth positions achieved by the preceding discrete step and so that the amount of repositioning required at each step involves an orthodontically optimal amount of force on the patient's dentition. As with the path definition step, this appliance calculation step can include interactions and even iterative interactions with the clinician (step 160). The operation of a process step 200 implementing this step will be described more fully below.

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Having calculated appliance definitions, the process 100 can proceed to the manufacturing step (step 180) in which appliances defined by the process are manufactured, or electronic or printed information is produced that can be used by a manual or automated process to define appliance configurations or changes to appliance configurations.

FIG. 2 illustrates a process 200 implementing the appliance-calculation step (FIG. 1, step 170) for polymeric shell aligners of the kind described in above-mentioned patent application Ser. No. 09/169,276. Inputs to the process include an initial aligner shape 202, various control parameters 204, and a desired end configuration for the teeth at the end of the current treatment path segment 206. Other inputs include digital models of the teeth in position in the jaw, models of the jaw tissue, and specifications of an initial aligner shape and of the aligner material. Using the input data, the process creates a finite element model of the aligner, teeth and tissue, with the aligner in place on the teeth (step 210). Next, the process applies a finite element analysis to the composite finite element model of aligner, teeth and tissue (step 220). The analysis runs until an exit condition is reached, at which time the process evaluates whether the teeth have reached the desired end position for the current path segment, or a position sufficiently close to the desired end position (step 230). If an acceptable end position is not reached by the teeth, the process calculates a new candidate aligner shape (step 240). If an acceptable end position is reached, the motions of the teeth calculated by the finite elements analysis are evaluated to determine whether they are orthodontically acceptable (step 232). If they are not, the process also proceeds to calculate a new candidate aligner shape (step 240). If the motions are orthodontically acceptable and the teeth have reached an acceptable position, the current aligner shape is compared to the previously calculated aligner shapes. If the current shape is the best solution so far (decision step 250), it is saved as the best candidate so far (step 260). If not, it is saved in an optional step as a possible intermediate result (step 252). If the current aligner shape is the best candidate so far, the process determines whether it is good enough to be accepted (decision step 270). If it is, the process exits. Otherwise, the process continues and calculates another candidate shape (step 240) for analysis.

The finite element models can be created using computer program application software available from a variety of vendors. For creating solid geometry models, computer aided engineering (CAE) or computer aided design (CAD) programs can be used, such as the AutoCAD® software products available from Autodesk, Inc., of San Rafael, Calif. For creating finite element models and analyzing them, program products from a number of vendors can be used, including the PolyFEM product available from CADSI of Coralville, Iowa, the Pro/Mechanica simulation software available from Parametric Technology Corporation of Waltham, Mass., the I-DEAS design software products available from Structural Dynamics Research Corporation (SDRC) of Cincinnati, Ohio, and the MSC/NASTRAN product available from MacNeal-Schwendler Corporation of Los Angeles, Calif.

FIG. 3 shows a process 300 of creating a finite element model that can be used to perform step 210 of the process 200 (FIG. 2). Input to the model creation process 300 includes input data 302 describing the teeth and tissues and input data 304 describing the aligner. The input data describing the teeth 302 include the digital models of the teeth; digital models of rigid tissue structures, if available; shape and viscosity specifications for a highly viscous fluid mod-

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eling the substrate tissue in which the teeth are embedded and to which the teeth are connected, in the absence of specific models of those tissues; and boundary conditions specifying the immovable boundaries of the model elements. In one implementation, the model elements include only models of the teeth, a model of a highly viscous embedding substrate fluid, and boundary conditions that define, in effect, a rigid container in which the modeled fluid is held.

10 A finite element model of the initial configuration of the teeth and tissue is created (step 310) and optionally cached for reuse in later iterations of the process (step 320). As was done with the teeth and tissue, a finite element model is created of the polymeric shell aligner (step 330). The input data for this model includes data specifying the material of which the aligner is made and the shape of the aligner (data input 304).

15 The model aligner is then computationally manipulated to place it over the modeled teeth in the model jaw to create a composite model of an in-place aligner (step 340). Optionally, the forces required to deform the aligner to fit over the teeth, including any hardware attached to the teeth, are computed and used as a figure of merit in measuring the acceptability of the particular aligner configuration. In a simpler alternative, however, the aligner deformation is modeled by applying enough force to its insides to make it large enough to fit over the teeth, placing the model aligner over the model teeth in the composite model, setting the conditions of the model teeth and tissue to be infinitely rigid, and allowing the model aligner to relax into position over the fixed teeth. The surfaces of the aligner and the teeth are modeled to interact without friction at this stage, so that the aligner model achieves the correct initial configuration over the model teeth before finite element analysis is begun to find a solution to the composite model and compute the movement of the teeth under the influence of the distorted aligner.

20 FIG. 4 shows a process 400 for calculating the shape of a next aligner that can be used in the aligner calculations, 25 step 240 of process 200 (FIG. 2). A variety of inputs are used to calculate the next candidate aligner shape. These include inputs 402 of data generated by the finite element analysis solution of the composite model and data 404 defined by the current tooth path. The data 402 derived from the finite element analysis includes the amount of real elapsed time over which the simulated repositioning of the teeth took place; the actual end tooth positions calculated by the analysis; the maximum linear and torsional force applied to each tooth; the maximum linear and angular velocity of each tooth. From the input path information, the input data 404 includes the initial tooth positions for the current path segment, the desired tooth positions at the end of the current path segment, the maximum allowable displacement velocity for each tooth, and the maximum allowable force of each kind for each tooth.

25 If a previously evaluated aligner was found to violate one or more constraints, additional input data 406 can optionally be used by the process 400. This data 406 can include information identifying the constraints violated by, and any identified suboptimal performance of, the previously evaluated aligner.

30 Having received the initial input data (step 420), the process iterates over the movable teeth in the model. (Some of the teeth may be identified as, and constrained to be, immobile.) If the end position and dynamics of motion of the currently selected tooth by the previously selected aligner is

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acceptable ("yes" branch of decision step 440), the process continues by selecting for consideration a next tooth (step 430) until all teeth have been considered ("done" branch from step 430 to step 470). Otherwise ("no" branch from step 440), a change in the aligner is calculated in the region of the currently selected tooth (step 450). The process then moves back to select the next current tooth (step 430) as has been described.

When all of the teeth have been considered, the aggregate changes made to the aligner are evaluated against previously defined constraints (step 470), examples of which have already been mentioned. Constraints can be defined with reference to a variety of further considerations, such as manufacturability. For example, constraints can be defined to set a maximum or minimum thickness of the aligner material, or to set a maximum or minimum coverage of the aligner over the crowns of the teeth. If the aligner constraints are satisfied, the changes are applied to define a new aligner shape (step 490). Otherwise, the changes to the aligner are revised to satisfy the constraints (step 480), and the revised changes are applied to define the new aligner shape (step 490).

FIG. 5A illustrates one implementation of the step of computing an aligner change in a region of a current tooth (step 450). In this implementation, a rule-based inference engine 456 is used to process the input data previously described (input 454) and a set of rules 452a-452n in a rule base of rules 452. The inference engine 456 and the rules 452 define a production system which, when applied to the factual input data, produces a set of output conclusions that specify the changes to be made to the aligner in the region of the current tooth (output 458).

Rules 452 have the conventional two-part form: an if-part defining a condition and a then-part defining a conclusion or action that is asserted if the condition is satisfied. Conditions can be simple or they can be complex conjunctions or disjunctions of multiple assertions. An exemplary set of rules, which defines changes to be made to the aligner, includes the following: if the motion of the tooth is too slow, add driving material to the aligner opposite the desired direction of motion; if the motion of the tooth is too slow, add driving material to overcorrect the position of the tooth; if the tooth is too far short of the desired end position, add material to overcorrect; if the tooth has been moved too far past the desired end position, add material to stiffen the aligner where the tooth moves to meet it; if a maximum amount of driving material has been added, add material to overcorrect the repositioning of the tooth and do not add driving material; if the motion of the tooth is in a direction other than the desired direction, remove and add material so as to redirect the tooth.

In an alternative embodiment, illustrated in FIGS. 5B and 5C, an absolute configuration of the aligner is computed, rather than an incremental difference. As shown in FIG. 5B, a process 460 computes an absolute configuration for an aligner in region of a current tooth. Using input data that has already been described, the process computes the difference between the desired end position and the achieved end position of the current tooth (462). Using the intersection of the tooth center line with the level of the gum tissue as the point of reference, the process computes the complement of the difference in all six degrees of freedom of motion, namely three degrees of translation and three degrees of rotation (step 464). Next, the model tooth is displaced from its desired end position by the amounts of the complement differences (step 466), which is illustrated in FIG. 5D.

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FIG. 5D shows a planar view of an illustrative model aligner 60 over an illustrative model tooth 62. The tooth is in its desired end position and the aligner shape is defined by the tooth in this end position. The actual motion of the tooth calculated by the finite element analysis is illustrated as placing the tooth in position 64 rather than in the desired position 62. A complement of the computed end position is illustrated as position 66. The next step of process 460 (FIG. 5B) defines the aligner in the region of the current tooth in this iteration of the process by the position of the displaced model tooth (step 468) calculated in the preceding step (466). This computed aligner configuration in the region of the current tooth is illustrated in FIG. 5D as shape 68 which is defined by the repositioned model tooth in position 66.

A further step in process 460, which can also be implemented as a rule 452 (FIG. 5A), is shown in FIG. 5C. To move the current tooth in the direction of its central axis, the size of the model tooth defining that region of the aligner, or the amount of room allowed in the aligner for the tooth, is made smaller in the area away from which the process has decided to move the tooth (step 465).

As shown in FIG. 6, the process 200 of computing the shape for an aligner for a step in a treatment path is one step in an overall process 600 of computing the shapes of a series of aligners. This overall process 600 begins with an initialization step 602 in which initial data, control and constraint values are obtained.

When an aligner configuration has been found for each step or segment of the treatment path (step 604), the overall process 600 determines whether all of the aligners are acceptable (step 606). If they are, the process exits and is complete. Otherwise, the process optionally undertakes a set of steps 610 in an attempt to calculate a set of acceptable aligners.

First, one or more of the constraints on the aligners is relaxed (step 612). Then, for each path segment with an unacceptable aligner, the process 200 of shaping an aligner is performed with the new constraints (step 614). If all the aligners are now acceptable, the overall process 600 exits (step 616).

Aligners may be unacceptable for a variety of reasons, some of which are handled by the overall process. For example, if any impossible movements were required (decision step 620), that is, if the shape calculation process 200 was required to effect a motion for which no rule or adjustment was available, the process 600 proceeds to execute a module that calculates the configuration of a hardware attachment to the subject tooth to which forces can be applied to effect the required motion (step 640). Because adding hardware can have an effect that is more than local, when hardware is added to the model, the outer loop of the overall process 600 is executed again (step 642).

If no impossible movements were required ("no" branch from step 620), the process transfers control to a path definition process (such as step 150, FIG. 1) to redefine those parts of the treatment path having unacceptable aligners (step 630). This step can include both changing the increments of tooth motion, i.e., changing the segmentation, on the treatment path, changing the path followed by one or more teeth in the treatment path, or both. After the treatment path has been redefined, the outer loop of the overall process is executed again (step 632). The recalculation is advantageously limited to recalculating only those aligners on the redefined portions of the treatment path. If all the aligners are now acceptable, the overall process exits (step 634). If unacceptable aligners still remain, the overall process can be

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repeated until an acceptable set of aligners is found or an iteration limit is exceeded (step 650). At this point, as well as at other point in the processes that are described in this specification, such as at the computation of additional hardware (step 640), the process can interact with a human operator, such as a clinician or technician, to request assistance (step 652). Assistance that an operator provides can include defining or selecting suitable attachments to be attached to a tooth or a bone, defining an added elastic element to provide a needed force for one or more segments of the treatment path, suggesting an alteration to the treatment path, either in the motion path of a tooth or in the segmentation of the treatment path, and approving a deviation from or relaxation of an operative constraint.

As was mentioned above, the overall process 600 is defined and parameterized by various items of input data (step 602). In one implementation, this initializing and defining data includes the following items: an iteration limit for the outer loop of the overall process; specification of figures of merit that are calculated to determine whether an aligner is good enough (see FIG. 2, step 270); a specification of the aligner material; a specification of the constraints that the shape or configuration of an aligner must satisfy to be acceptable; a specification of the forces and positioning motions and velocities that are orthodontically acceptable; an initial treatment path, which includes the motion path for each tooth and a segmentation of the treatment path into segments, each segment to be accomplished by one aligner; a specification of the shapes and positions of any anchors installed on the teeth or otherwise; and a specification of a model for the jaw bone and other tissues in or on which the teeth are situated (in the implementation being described, this model consists of a model of a viscous substrate fluid in which the teeth are embedded and which has boundary conditions that essentially define a container for the fluid).

Optionally, other features are added to the tooth model data sets to produce desired features in the aligners. For example, it may be desirable to add digital wax patches to define cavities or recesses to maintain a space between the aligner and particular regions of the teeth or jaw. It may also be desirable to add digital wax patches to define corrugated or other structural forms to create regions having particular stiffness or other structural properties. In manufacturing processes that rely on generation of positive models to produce the repositioning appliance, adding a wax patch to the digital model will generate a positive mold that has the same added wax patch geometry. This can be done globally in defining the base shape of the aligners or in the calculation of particular aligner shapes. One feature that can be added is a rim around the gumline, which can be produced by adding a digital model wire at the gumline of the digital model teeth from which the aligner is manufactured. When an aligner is manufactured by pressure fitting polymeric material over a positive physical model of the digital teeth, the wire along the gumlines causes the aligner to have a rim around it providing additional stiffness along the gumline.

In another optional manufacturing technique, two sheets of material are pressure fit over the positive tooth model, where one of the sheets is cut along the apex arch of the aligner and the other is overlaid on top. This provides a double thickness of aligner material along the vertical walls of the teeth.

The changes that can be made to the design of an aligner are constrained by the manufacturing technique that will be used to produce it. For example, if the aligner will be made by pressure fitting a polymeric sheet over a positive model, the thickness of the aligner is determined by the thickness of

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the sheet. As a consequence, the system will generally adjust the performance of the aligner by changing the orientation of the model teeth, the sizes of parts of the model teeth, the position and selection of attachments, and the addition or removal of material (e.g., adding wires or creating dimples) to change the structure of the aligner. The system can optionally adjust the aligner by specifying that one or more of the aligners are to be made of a sheet of a thickness other than the standard one, to provide more or less force to the teeth. On the other hand, if the aligner will be made by a stereo lithography process, the thickness of the aligner can be varied locally, and structural features such as rims, dimples, and corrugations can be added without modifying the digital model of the teeth.

15 The system can also be used to model the effects of more traditional appliances such as retainers and braces and therefore be used to generate optimal designs and treatment programs for particular patients.

20 The data processing aspects of the invention can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of them. Data processing apparatus of the invention can be implemented in a computer program product tangibly embodied in a machine-readable storage device for execution by a programmable processor; and data processing method steps of the invention can be performed by a programmable processor executing a program of instructions to perform functions of the invention by operating on input data and generating output. The data processing aspects of the invention can be 25 implemented advantageously in one or more computer programs that are executable on a programmable system including at least one programmable processor coupled to receive data and instructions from and to transmit data and instructions to a data storage system, at least one input device, and at least one output device. Each computer program can be 30 implemented in a high-level procedural or object-oriented programming language, or in assembly or machine language, if desired; and, in any case, the language can be a compiled or interpreted language. Suitable processors include, by way of example, both general and special purpose microprocessors. Generally, a processor will receive instructions and data from a read-only memory and/or a random access memory. Storage devices suitable for tangibly embodying computer program instructions and data include all forms of nonvolatile memory, including by way of example semiconductor memory devices, such as EPROM, EEPROM, and flash memory devices; magnetic disks such as internal hard disks and removable disks; magneto-optical disks; and CD-ROM disks. Any of the foregoing can be supplemented by, or incorporated in, 35 ASICs (application-specific integrated circuits).

To provide for interaction with a user, the invention can be implemented using a computer system having a display device such as a monitor or LCD (liquid crystal display) screen for displaying information to the user and input devices by which the user can provide input to the computer system such as a keyboard, a two-dimensional pointing device such as a mouse or a trackball, or a three-dimensional pointing device such as a data glove or a gyroscopic mouse. 40 The computer system can be programmed to provide a graphical user interface through which computer programs interact with users. The computer system can be programmed to provide a virtual reality, three-dimensional display interface.

45 50 55 60 65 The invention has been described in terms of particular embodiments. Other embodiments are within the scope of the following claims. For example, the steps of the invention

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can be performed in a different order and still achieve desirable results.

What is claimed is:

1. A computer-implemented method for segmenting an orthodontic treatment path into segments, comprising:
 - for each tooth in a set of teeth, receiving a tooth path for the motion of the tooth from an initial position to a final position;
 - calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and
 - generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.
2. The method of claim 1, further comprising:
 - determining for each appliance whether it is clinically acceptable.
3. The method of claim 2, further comprising:
 - if an appliance is not clinically acceptable, providing as output to a user a description of the appliance and receiving as input from the user a suggested modification to the appliance that is not clinically acceptable.
4. The method of claim 2, further comprising:
 - if an appliance is not clinically acceptable, calculating a new segmentation to change the treatment segment corresponding to the appliance that is not clinically acceptable.
5. The method of claim 4, wherein calculating a new segmentation comprises determining that the forces that can be generated by the appliance on the then-existing configuration of teeth is incapable of effecting the repositioning that is represented by the treatment segment corresponding the appliance that is not clinically acceptable.
6. The method of claim 1, further comprising:
 - displaying the segmentation to a user; and
 - receiving input from the user changing the segmentation.
7. The method of claim 1, further comprising:
 - displaying the segmentation to a clinician in an animation of the positions and paths.
8. The method of claim 7, further comprising:
 - receiving from the clinician input to specify constraints to be applied to the segmented paths.
9. The method of claim 1, wherein the tooth paths are optimized in the aggregate so that the teeth are moved with the least amount of round-tripping to bring the teeth from their initial positions to their final positions.
10. The method of claim 1, wherein the threshold limits of linear and rotational translation are initialized with default values based on the nature of the appliance to be used.
11. The method of claim 1, wherein at least one of the threshold limits is given an individually tailored limit value calculated using patient-specific data.
12. A computer program product, tangibly stored on a computer-readable medium, comprising instructions operable to cause a computer to:
 - receive a tooth path for the motion of the tooth from an initial position to a final position, for each tooth in a set of teeth;
 - calculate a segmentation of the aggregate tooth paths into treatment a plurality of segments so that each tooth's motion with a segment stays within threshold limits of linear and rotational translation; and
 - generate a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.
13. The product of claim 12, further comprising instructions operable to cause a computer to:
 - determine for each appliance whether it is clinically acceptable.
14. The product of claim 13, further comprising instructions operable to cause a computer to:
 - provide as output to a user a description of an appliance that is not clinically acceptable and receive as input from the user a suggested modification to the appliance that is not clinically acceptable.
15. The product of claim 13, further comprising instructions operable to cause a computer to:
 - calculate a new segmentation to change the treatment segment corresponding to an appliance that is not clinically acceptable.
16. The product of claim 15, wherein the instructions to calculate a new segmentation comprises instructions to determine that the forces that can be generated by the appliance on the then-existing configuration of teeth is incapable of effecting the repositioning that is represented by the treatment segment corresponding the appliance that is not clinically acceptable.
17. The product of claim 12, further comprising instructions operable to cause a computer to:
 - display the segmentation to a user; and
 - receive input from the user changing the segmentation.
18. The product of claim 12, further comprising instructions operable to cause a computer to:
 - display the segmentation to a clinician in an animation of the positions and paths.
19. The product of claim 18, further comprising instructions operable to cause a computer to:
 - receive from the clinician input to specify constraints to be applied to the segmented paths.
20. The product of claim 12, wherein the tooth paths are optimized in the aggregate so that the teeth are moved with the least amount of round-tripping to bring the teeth from their initial positions to their final positions.
21. The product of claim 12, wherein the threshold limits of linear and rotational translation are initialized with default values based on the nature of the appliance to be used.
22. The product of claim 12, wherein at least one of the threshold limits is given an individually tailored limit value calculated using patient-specific data.
23. A system for segmenting an orthodontic treatment path into segments, comprising:
 - means for receiving a tooth path for the motion of the tooth from an initial position to a final position, for each tooth in a set of teeth;
 - means for calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and
 - means for generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells hav-

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motion with a segment stays within threshold limits of linear and rotational translation; and

generate a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells having cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

13. The product of claim 12, further comprising instructions operable to cause a computer to:

determine for each appliance whether it is clinically acceptable.

14. The product of claim 13, further comprising instructions operable to cause a computer to:

provide as output to a user a description of an appliance that is not clinically acceptable and receive as input from the user a suggested modification to the appliance that is not clinically acceptable.

15. The product of claim 13, further comprising instructions operable to cause a computer to:

calculate a new segmentation to change the treatment segment corresponding to an appliance that is not clinically acceptable.

16. The product of claim 15, wherein the instructions to calculate a new segmentation comprises instructions to determine that the forces that can be generated by the appliance on the then-existing configuration of teeth is incapable of effecting the repositioning that is represented by the treatment segment corresponding the appliance that is not clinically acceptable.

17. The product of claim 12, further comprising instructions operable to cause a computer to:

display the segmentation to a user; and

receive input from the user changing the segmentation.

18. The product of claim 12, further comprising instructions operable to cause a computer to:

display the segmentation to a clinician in an animation of the positions and paths.

19. The product of claim 18, further comprising instructions operable to cause a computer to:

receive from the clinician input to specify constraints to be applied to the segmented paths.

20. The product of claim 12, wherein the tooth paths are optimized in the aggregate so that the teeth are moved with the least amount of round-tripping to bring the teeth from their initial positions to their final positions.

21. The product of claim 12, wherein the threshold limits of linear and rotational translation are initialized with default values based on the nature of the appliance to be used.

22. The product of claim 12, wherein at least one of the threshold limits is given an individually tailored limit value calculated using patient-specific data.

23. A system for segmenting an orthodontic treatment path into segments, comprising:

means for receiving a tooth path for the motion of the tooth from an initial position to a final position, for each tooth in a set of teeth;

means for calculating a segmentation of the aggregate tooth paths into a plurality of treatment segments so that each tooth's motion within a segment stays within threshold limits of linear and rotational translation; and

means for generating a plurality of appliances, at least one or more appliances for each treatment segment, wherein the appliances comprise polymeric shells hav-

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ing cavities and wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition the teeth from one arrangement to a successive arrangement.

24. The system of claim 23, further comprising:
means for determining for each appliance whether it is
clinically acceptable.

25. The system of claim 24, further comprising:
means for providing as output to a user a description of an
appliance that is not clinically acceptable and receiving
as input from the user a suggested modification to the
appliance that is not clinically acceptable.

26. The system of claim 24, further comprising:
means for calculating a new segmentation to change the
treatment segment corresponding to an appliance that is
not clinically acceptable.

27. The system of claim 26, wherein the means for
calculating a new segmentation comprises means for deter-
mining that the forces that can be generated by the appliance
on the then-existing configuration of teeth is incapable of
effecting the repositioning that is represented by the treat-
ment segment corresponding the appliance that is not clin-
ically acceptable.

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28. The system of claim 23, further comprising:
means for displaying the segmentation to a user; and
means for receiving input from the user changing the
segmentation.

29. The system of claim 23, further comprising:
means for displaying the segmentation to a clinician in an
animation of the positions and paths.

30. The system of claim 29, further comprising:
means for receiving from the clinician input to specify
constraints to be applied to the segmented paths.

31. The system of claim 23, wherein the tooth paths are
optimized in the aggregate so that the teeth are moved with
the least amount of round-tripping to bring the teeth from
their initial positions to their final positions.

32. The system of claim 23, wherein the threshold limits
of linear and rotational translation are initialized with default
values based on the nature of the appliance to be used.

33. The system of claim 23, wherein at least one of the
threshold limits is given an individually tailored limit value
calculated using patient-specific data.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,471,511 B1
DATED : October 29, 2002
INVENTOR(S) : Chishti et al.

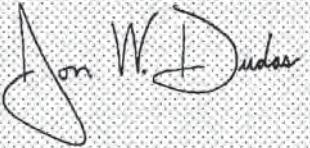
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page.

Item [63], **Related U.S. Application Data**, delete "Continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893" and insert
-- Continuation-in-part of PCT application No. PCT/US98/12861, filed on Jun. 19, 1998, which is a Continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893" --.

Signed and Sealed this
Eighteenth Day of April, 2006



JON W. DUDAS

Director of the United States Patent and Trademark Office

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U.S. Patent

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Sheet 1 of 7

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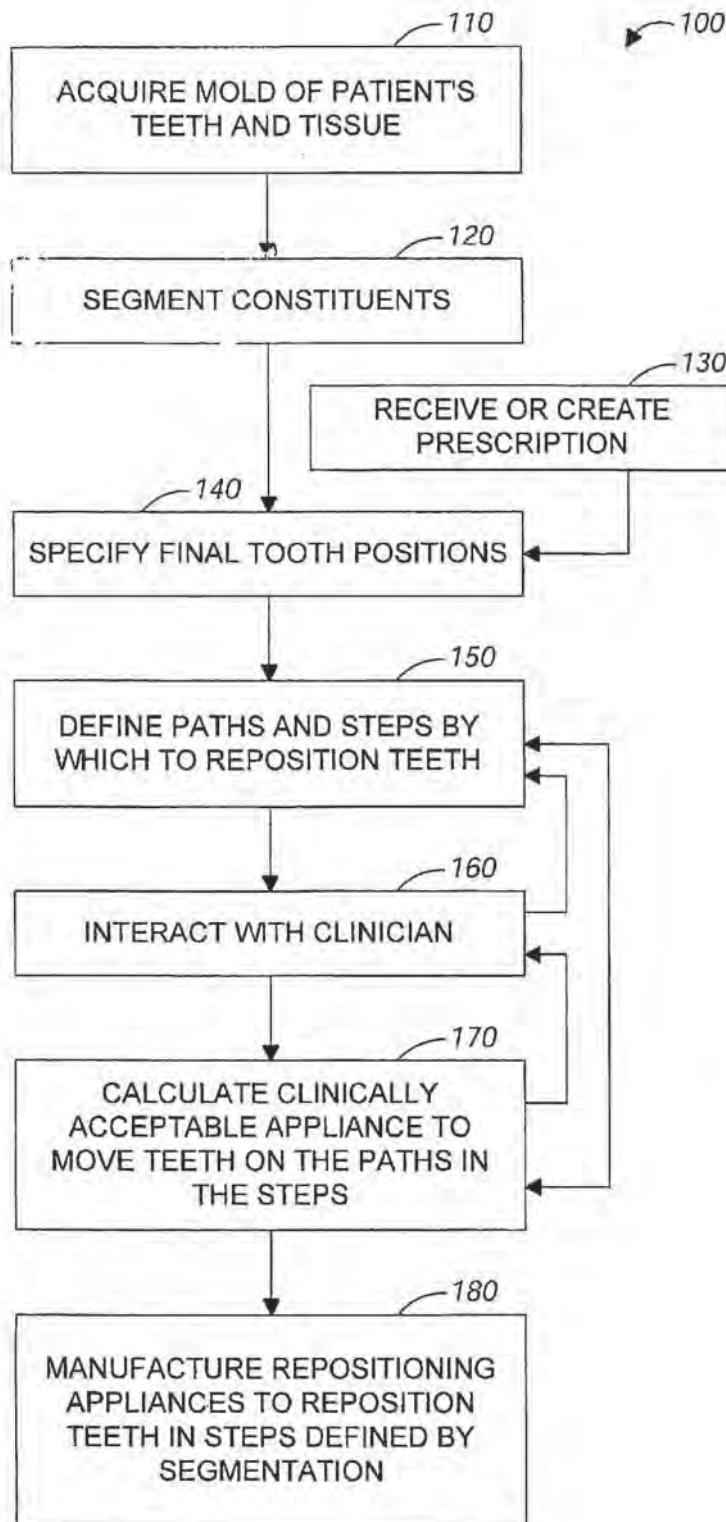


FIG. 1

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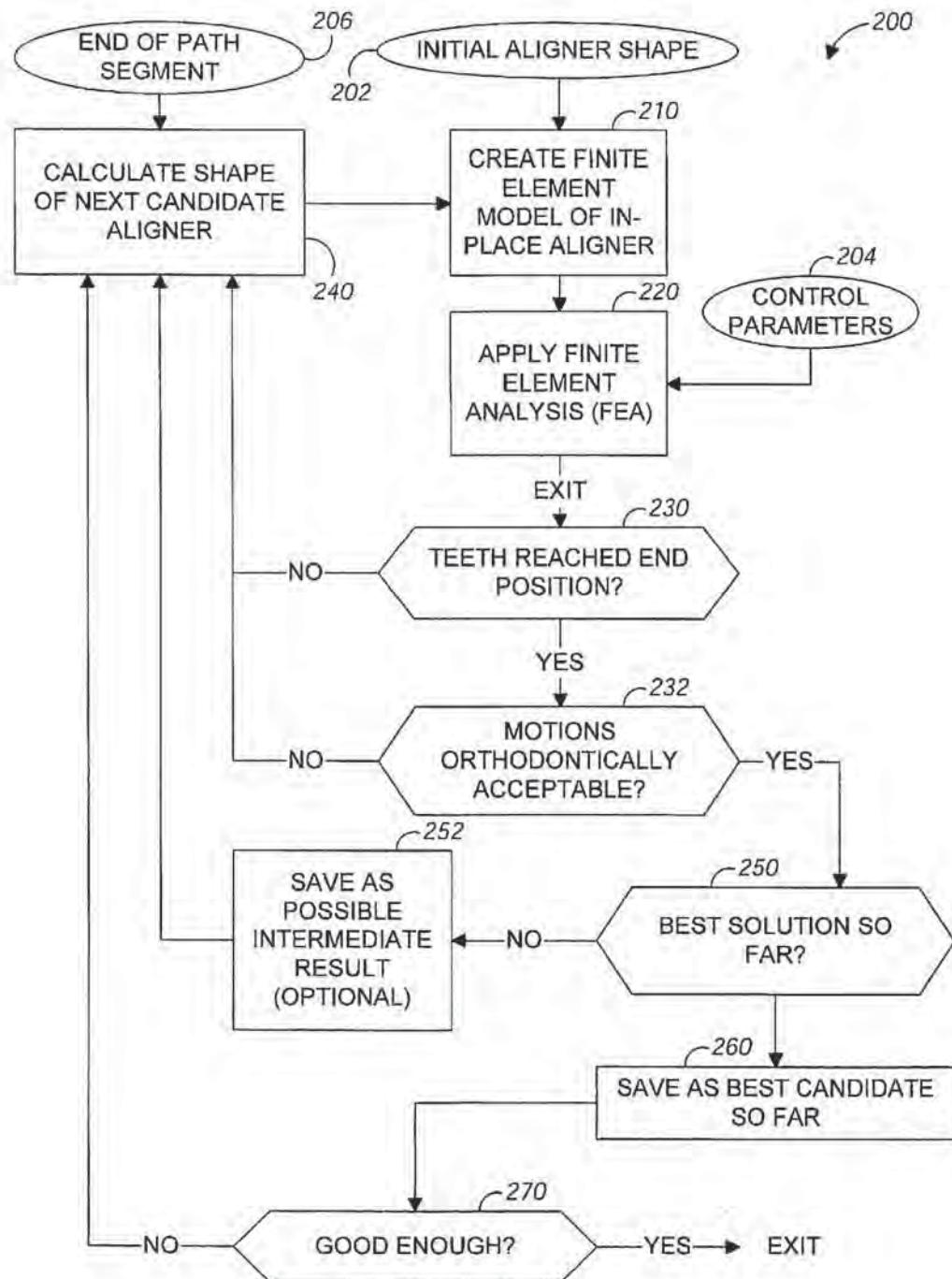


FIG. 2

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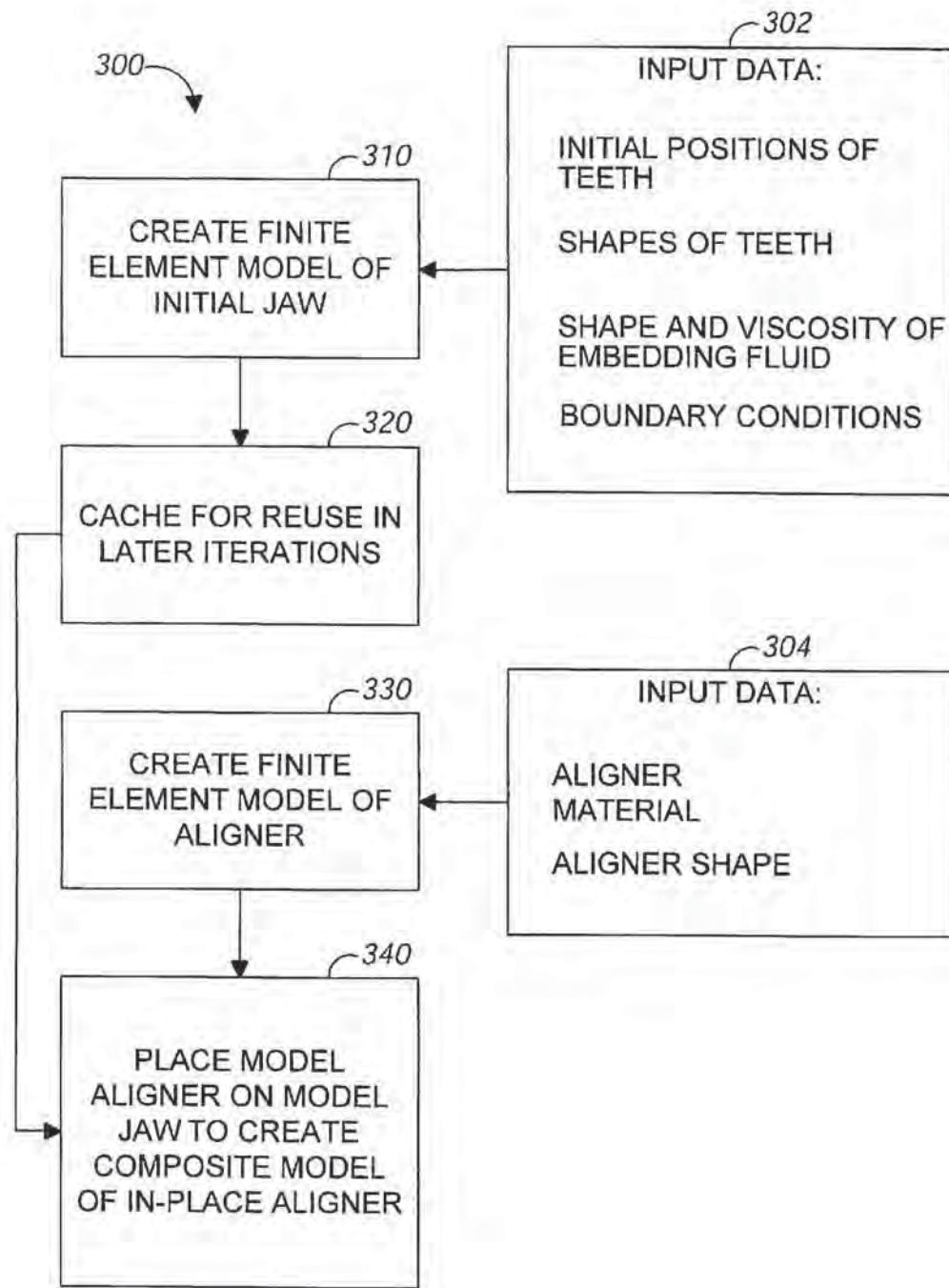


FIG. 3

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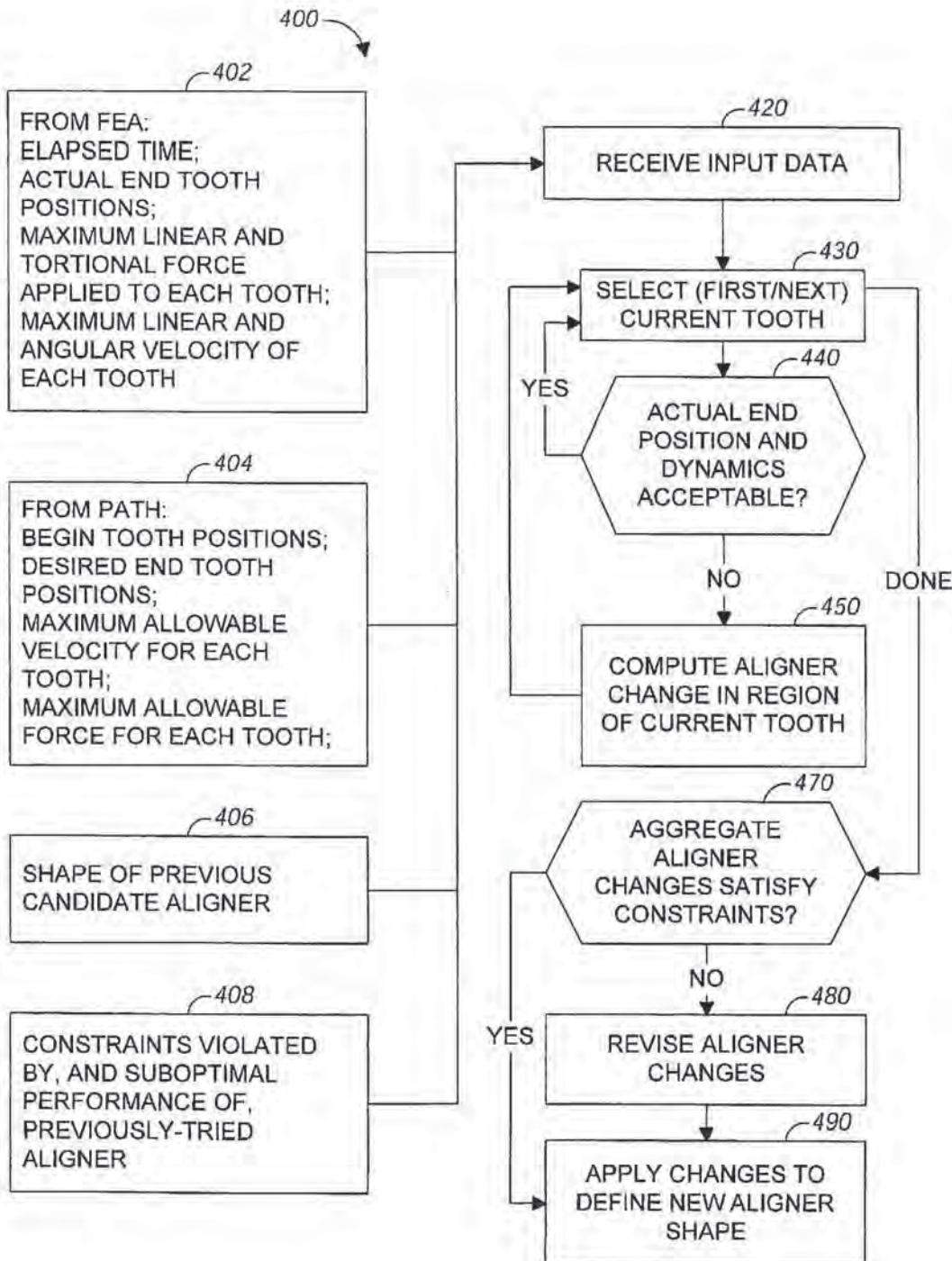


FIG. 4

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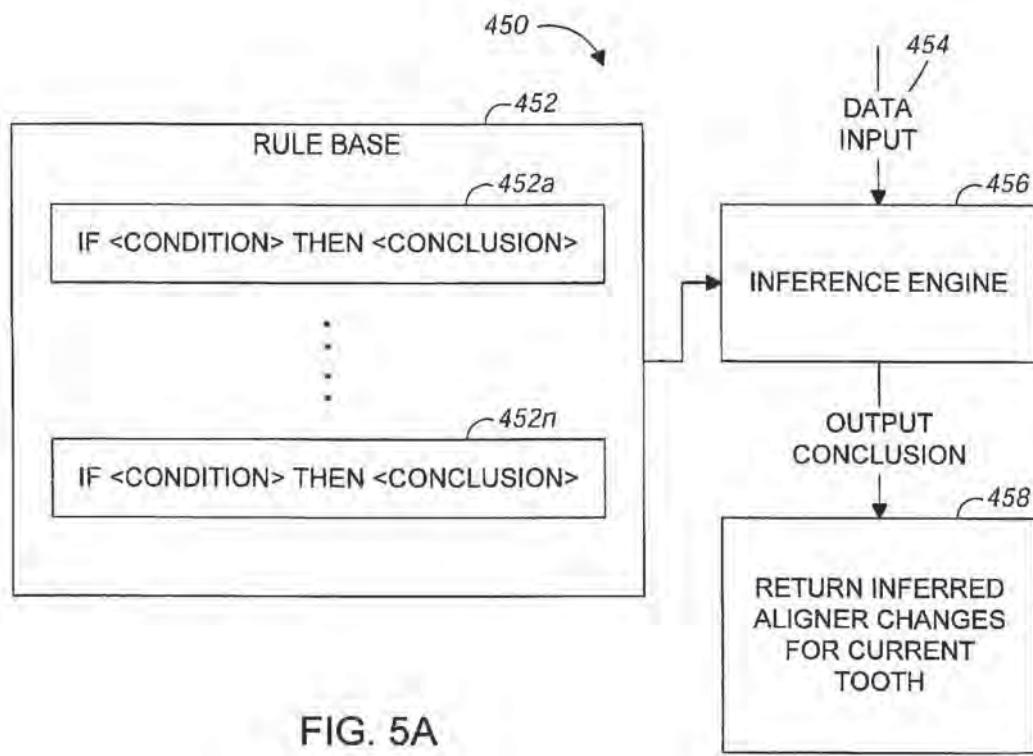


FIG. 5A

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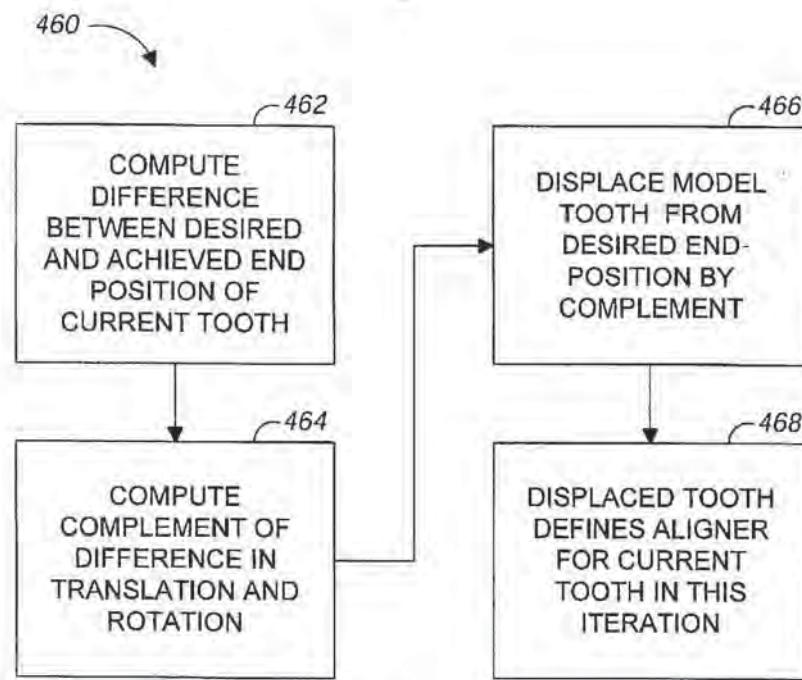


FIG. 5B

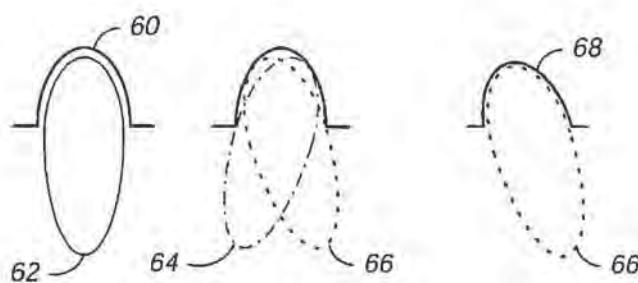
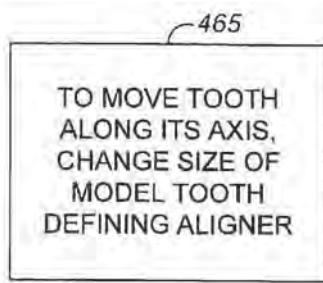


FIG. 5C

FIG. 5D

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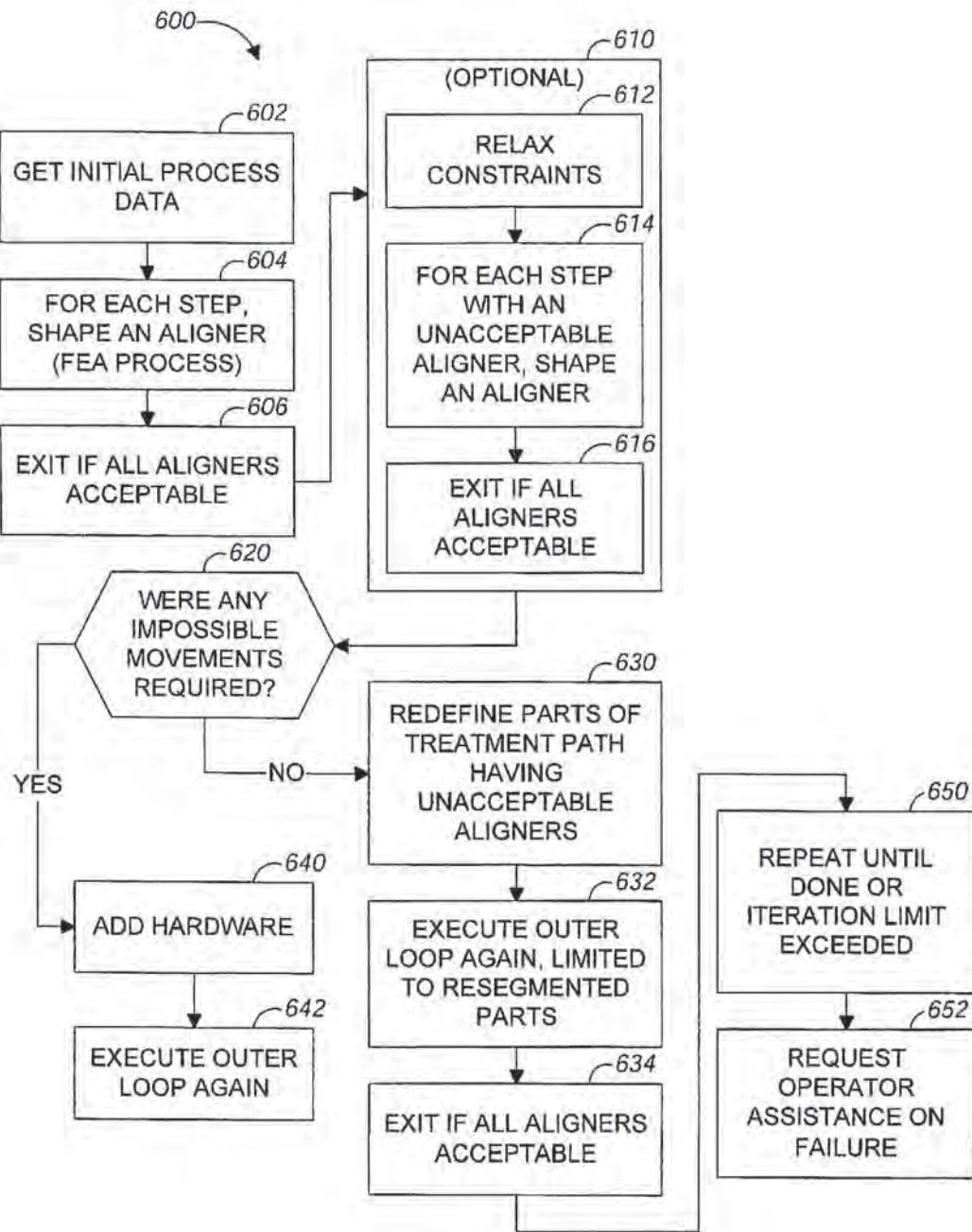
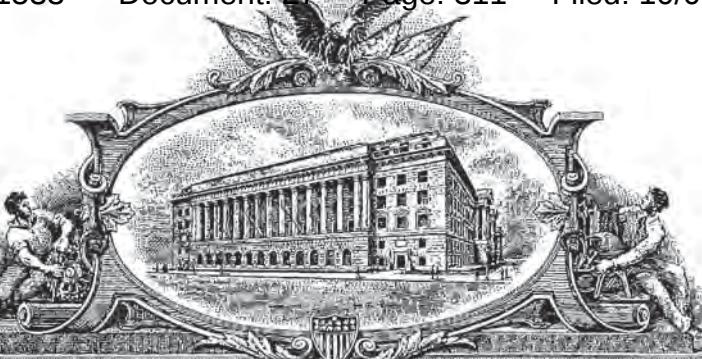


FIG. 6

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THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
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U.S. PATENT: 6,626,666

ISSUE DATE: September 30, 2003

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office


W. MONTGOMERY
Certifying Officer



A2968



US006626666B2

(12) United States Patent
Chishti et al.(10) Patent No.: US 6,626,666 B2
(45) Date of Patent: *Sep. 30, 2003(54) METHOD AND SYSTEM FOR
INCREMENTALLY MOVING TEETH

(75) Inventors: Muhammad Chishti, Menlo Park, CA (US); Apostolos Lerios, Stanford, CA (US); Brian Freyburger, Palo Alto, CA (US); Kelsey Wirth, Menlo Park, CA (US); Richard Ridgley, Los Altos, CA (US)

(73) Assignee: Align Technology, Inc., Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 117 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 09/757,044

(22) Filed: Jan. 8, 2001

(65) Prior Publication Data

US 2001/0008751 A1 Jul. 19, 2001

Related U.S. Application Data

(60) Continuation of application No. 09/298,268, filed on Apr. 23, 1999, now Pat. No. 6,217,325, which is a division of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.
(60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) Int. Cl. 7 A61C 3/00

(52) U.S. Cl. 433/24
(58) Field of Search 433/24, 213, 215

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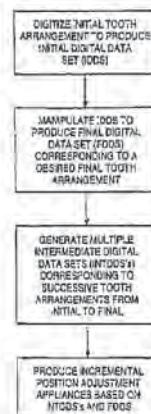
Primary Examiner—John J. Wilson

(74) Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

(57) ABSTRACT

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

21 Claims, 9 Drawing Sheets



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METHOD AND SYSTEM FOR INCREMENTALLY MOVING TEETH**CROSS-REFERENCES TO RELATED APPLICATIONS**

The present application is a continuation of application Ser. No. 09/298,268, filed Apr. 23, 1999 now U.S. Pat. No. 6,217,325, which was a division of application Ser. No. 08/947,080, filed Oct. 8, 1997 now U.S. Pat. No. 5,975,893, which is a continuation of provisional Application No. 60/050,342; filed on Jun. 20, 1997, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically scheduled with the orthodontist, dentist, and/or X-ray laboratory so that X-rays and photographs of the patient's teeth and jaw structure can be taken. Also during this preliminary meeting, or possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well bonded to the teeth.

The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontia as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tight-

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ening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter. Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, La. 70125, and Tru-Tain Plastics, Rochester, Minn. 55902. The manufacture of orthodontic positioners is described in U.S. Pat. Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.* 30:673-680; Cureton (1996) *J. Clin. Orthodon.* 30:390-395; Chiappone (1980) *J. Clin. Orthodon.* 14:121-133; Shilliday (1971) *Am. J. Orthodontics* 59:596-599; Wells (1970) *Am. J. Orthodontics* 58:351-366; and Cottingham (1969) *Am. J. Orthodontics* 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics* 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459.

U.S. Pat. Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Pat. Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

SUMMARY OF THE INVENTION

The present invention provides improved methods and systems for repositioning teeth from an initial tooth arrange-

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ment to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, certain of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

Systems according to the present invention will include at least a first appliance having a geometry selected to reposition a patient's teeth from the initial tooth arrangement to a first intermediate arrangement where individual teeth will be incrementally repositioned. The system will further comprise at least one intermediate appliance having a geometry selective to progressively reposition teeth from the first intermediate arrangement to one or more successive intermediate arrangements. The system will still further comprise a final appliance having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. In some cases, it will be desirable to form the final appliance or several appliances to "over correct" the final tooth position, as discussed in more detail below.

As will be described in more detail below in connection with the methods of the present invention, the systems may be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single package or system. The order in which the appliances are to be used will be clearly marked, (e.g. by sequential numbering) so that the patient can place the appliances over his or her teeth at a frequency prescribed by the orthodontist or other treating professional. Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller,

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successive steps while still reducing the time spent by the treating professional with the individual patient. Moreover, the ability to use polymeric shell appliances which are more comfortable, less visible, and removable by the patient, greatly improves patient compliance, comfort, and satisfaction.

According to a method of the present invention, a patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment appliances in the patient's mouth. Conveniently, the appliances are not affixed and the patient may place and replace the appliances at any time during the procedure. The first appliance of the series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. After the first intermediate arrangement is approached or achieved, one or more additional (intermediate) appliances will be successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). The treatment will be finished by placing a final appliance in the patient's mouth, where the final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to the final tooth arrangement. The final appliance or several appliances in the series may have a geometry or geometries selected to over correct the tooth arrangement, i.e. have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e. to permit some movement of individual teeth back toward their pre-corrected positions. Over correction may also be beneficial to speed the rate of correction, i.e. by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, treatment can be terminated before the teeth reach the positions defined by the final appliance or appliances. The method will usually comprise placing at least two additional appliances, often comprising placing at least ten additional appliances, sometimes placing at least twenty-five additional appliances, and occasionally placing at least forty or more additional appliances. Successive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

Often, it may be desirable to replace the appliances at a time before the "end" tooth arrangement of that treatment stage is actually achieved. It will be appreciated that as the teeth are gradually repositioned and approach the geometry defined by a particular appliance, the repositioning force on the individual teeth will diminish greatly. Thus, it may be possible to reduce the overall treatment time by replacing an earlier appliance with the successive appliance at a time when the teeth have been only partially repositioned by the earlier appliance. Thus, the FDDS can actually represent an over correction of the final tooth position. This both speeds the treatment and can offset patient relapse.

In general, the transition to the next appliance can be based on a number of factors. Most simply, the appliances can be replaced on a predetermined schedule or at a fixed time interval (i.e. number of days for each appliance) determined at the outset based on an expected or typical

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patient response. Alternatively, actual patient response can be taken into account, e.g. a patient can advance to the next appliance when that patient no longer perceives pressure on their teeth from a current appliance, i.e. the appliance they have been wearing fits easily over the patient's teeth and the patient experiences little or no pressure or discomfort on his or her teeth. In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances, i.e. reduce the total number of appliances being used below the number determined at the outset. In this way, the overall treatment time for a particular patient can be reduced.

In another aspect, methods of the present invention comprise repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. The present invention provides improvements to such methods which comprise determining at the outset of treatment geometries for at least three of the appliances which are to be worn successively by a patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement. Preferably, at least four geometries will be determined in the outset, often at least ten geometries, frequently at least twenty-five geometries, and sometimes forty or more geometries. Usually, the tooth positions defined by the cavities in each successive geometry differ from those defined by the prior geometry by no more than 2 mm, preferably no more than 1 mm, and often no more than 0.5 mm, as defined above.

In yet another aspect, methods are provided for producing a digital data set representing a final tooth arrangement. The methods comprise providing an initial data set representing an initial tooth arrangement, and presenting a visual image based on the initial data set. The visual image is then manipulated to reposition individual teeth in the visual image. A final digital data set is then produced which represents the final tooth arrangement with repositioned teeth as observed in the visual image. Conveniently, the initial digital data set may be provided by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like. Preferably, the images will be three-dimensional images and digitization may be accomplished using conventional technology. Usually, the initial digital data set is provided by producing a plaster cast of the patient's teeth (prior to treatment) by conventional techniques. The plaster cast so produced may then be scanned using laser or other scanning equipment to produce a high resolution digital representation of the plaster cast of the patient's teeth. Use of the plaster cast is preferred since it does not expose the patient to X-rays or subject the patient to the inconvenience of an MRI scan.

Once the digital data set is acquired, an image can be presented and manipulated on a suitable computer system equipped with computer-aided design software, as described in greater detail below. The image manipulation will usually comprise defining boundaries about at least some of the individual teeth, and causing the images of the teeth to be moved relative to the jaw and other teeth by manipulation of the image via the computer. The image manipulation can be done entirely subjectively, i.e. the user may simply reposition teeth in an aesthetically and/or therapeutically desired manner based on observation of the image alone. Alternatively, the computer system could be provided with rules and algorithms which assist the user in repositioning

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the teeth. In some instances, it will be possible to provide rules and algorithms which reposition the teeth in a fully automatic manner, i.e. without user intervention. Once the individual teeth have been repositioned, a final digital data set representing the desired final tooth arrangement will be generated and stored.

A preferred method for determining the final tooth arrangement is for the treating professional to define the final tooth positions, e.g. by writing a prescription. The use of prescriptions for defining the desired outcomes of orthodontic procedures is well known in the art. When a prescription or other final designation is provided, the image can then be manipulated to match the prescription. In some cases, it would be possible to provide software which could interpret the prescription in order to generate the final image and thus the digital data set representing the final tooth arrangement.

In yet another aspect, methods according to the present invention are provided for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement. Such methods comprise providing a digital data set representing an initial tooth arrangement (which may be accomplished according to any of the techniques set forth above). A digital data set representing a final tooth arrangement is also provided. Such final digital data set may be determined by the methods described previously. The plurality of successive digital data sets are then produced based on the initial digital data set and the final digital data set. Usually, the successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences. Such interpolation may be performed over as many discrete stages as may be desired, usually at least three, often at least four, more often at least ten, sometimes at least twenty-five, and occasionally forty or more. Many times, the interpolation will be linear interpolation for some or all of the positional differences. Alternatively, the interpolation may be non-linear. The positional differences will correspond to tooth movements where the maximum linear movement of any point on a tooth is 2 mm or less, usually being 1 mm or less, and often being 0.5 mm or less.

Often, the user will specify certain target intermediate tooth arrangements, referred to as "key frames," which are incorporated directly into the intermediate digital data sets. The methods of the present invention then determine successive digital data sets between the key frames in the manner described above, e.g. by linear or non-linear interpolation between the key frames. The key frames may be determined by a user, e.g. the individual manipulating a visual image at the computer used for generating the digital data sets, or alternatively may be provided by the treating professional as a prescription in the same manner as the prescription for the final tooth arrangement.

In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements. Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrange-

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ments. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of non-hardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines.

In still another aspect, methods of the present invention for fabricating a dental appliance comprise providing a digital data set representing a modified tooth arrangement for a patient. A fabrication machine is then used to produce a positive model of the modified tooth arrangement based on the digital data set. The dental appliance is then produced as a negative of the positive model. The fabrication machine may be a stereolithography or other machine as described above, and the positive model is produced by conventional pressure or vacuum molding techniques.

In a still further aspect, methods for fabricating a dental appliance according to the present invention comprise providing a first digital data set representing a modified tooth arrangement for a patient. A second digital data set is then produced from the first digital data set, where the second data set represents a negative model of the modified tooth arrangement. The fabrication machine is then controlled based on the second digital data set to produce the dental appliance. The fabrication machine will usually rely on selectively hardening a non-hardened resin to produce the appliance. The appliance typically comprises a polymeric shell having a cavity shape to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

FIG. 1B illustrates a single tooth from FIG. 1A and defines how tooth movement distances are determined.

FIG. 1C illustrates the jaw of FIG. 1A together with an incremental position adjustment appliance which has been configured according to the methods of the present invention.

FIG. 2 is a block diagram illustrating the steps of the present invention for producing a system of incremental position adjustment appliances.

FIG. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

FIG. 4 is a flow chart illustrating an eraser tool for the methods herein.

FIG. 4A illustrates the volume of space which is being erased by the program of FIG. 4.

FIG. 5 is a flow chart illustrating a program for matching high-resolution and low-resolution components in the manipulation of data sets of FIG. 3.

FIG. 6 illustrates the method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances of the present invention.

FIG. 7 illustrates alternative processes for producing a plurality of appliances according to the methods of the present invention utilizing digital data sets representing the intermediate and final appliance designs.

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DESCRIPTION OF THE SPECIFIC EMBODIMENTS

According to the present invention, systems and methods are provided for incrementally moving teeth using a plurality of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

Referring now to FIG. 1A, a representative jaw 100 includes sixteen teeth 102. The present invention is intended to move at least some of these teeth from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this centerline (CL), the teeth may be moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally, the tooth may be rotated about the centerline, as represented by arrow 114. Thus, all possible free-form motions of the tooth can be performed. Referring now to FIG. 1B, the magnitude of any tooth movement achieved by the methods and devices of the present invention will be defined in terms of the maximum linear translation of any point P on a tooth 102. Each point Pi will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in FIG. 1A. That is, while the point will usually follow a non-linear path, there will be a linear distance between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P1 may in fact undergo a true side-to-side translation as indicated by arrow d1, while a second arbitrary point P2 may travel along an arcuate path, resulting in a final translation d2. Many aspects of the present invention are defined in terms of the maximum permissible movement of a point Pi induced by the methods in any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point Pi on the tooth which undergoes the maximum movement for that tooth in any treatment step.

Referring now to FIG. 1C, systems according to the present invention will comprise a plurality of incremental position adjustment appliances. The appliances are intended to effect incremental repositioning of individual teeth in the jaw as described generally above. In a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. The systems of the present invention, in contrast with prior apparatus and systems, will provide a plurality of such appliances intended to be worn by a patient successively in order to achieve the gradual tooth repositioning as described herein. A preferred appliance 100 will comprise a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably, but not necessarily, fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others of the teeth will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or

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teeth to be repositioned. In complex cases, however, many or most of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance. Additionally, the gums and/or the palette can serve as an anchor region, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

The polymeric appliance 100 of FIG. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, Tru-Tain Plastics, Rochester, Minn. 55902. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor. Specific methods for producing the appliances 100 are described hereinafter.

Referring now to FIG. 2, the overall method of the present invention for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the IDDS. The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. Methods for digitizing such conventional images to produce data sets useful in the present invention are well known and described in the patent and medical literature. Usually, however, the present invention will rely on first obtaining a plaster cast of the patient's teeth by well known techniques, such as those described in Graber, Orthodontics: Principle and Practice, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415. After the tooth casting is obtained, it can be digitally scanned using a conventional laser scanner or other range acquisition system to produce the IDDS. The data set produced by the range acquisition system may, of course, be converted to other formats to be compatible with the software which is used for manipulating images within the data set, as described in more detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Pat. No. 5,605,459, the full disclosure of which is incorporated herein by reference.

There are a variety of range acquisition systems, generally categorized by whether the process of acquisition requires contact with the three dimensional object. A contact-type range acquisition system utilizes a probe, having multiple degrees of translational and/or rotational freedom. By recording the physical displacement of the probe as it is drawn across the sample surface, a computer-readable representation of the sample object is made. A non-contact-type range acquisition device can be either a reflective-type or transmissive-type system. There are a variety of reflective systems in use. Some of these reflective systems utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Those non-contact-type systems working by reflected optical energy further contain special instrumentation configured to permit certain measuring techniques to be performed (e.g., imaging radar, triangulation and interferometry).

A preferred range acquisition system is an optical, reflective, non-contact-type scanner. Non-contact-type scan-

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ners are preferred because they are inherently nondestructive (i.e., do not damage the sample object), are generally characterized by a higher capture resolution and scan a sample in a relatively short period of time. One such scanner is the Cyberware Model 15 manufactured by Cyberware, Inc., Monterey, Calif.

Either non-contact-type or contact-type scanners may also include a color camera, that when synchronized with the scanning capabilities, provides a means for capturing, in digital format, a color representation of the sample object. The importance of this further ability to capture not just the shape of the sample object but also its color is discussed below.

The methods of the present invention will rely on manipulating the IDDS at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present invention.

Referring again to FIG. 2, after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDS's, as described in more detail below.

FIG. 3 illustrates a representative technique for manipulating the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner will be in a high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data set representing the IDDS at a lower resolution will be created. The user will manipulate the lower resolution images while the computer will update the high resolution data set as necessary. The user can also view/manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS will also be converted into a quad edge data structure if not already present in that form. A quad edge

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data structure is a standard topological data structure defined in Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and other oral tissue, the user will usually delete structure which is unnecessary for image manipulation and/or final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI. Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and/or which teeth will be extracted. Shaving allows the patient to maintain their teeth when only a small amount of space is needed. Typically, extraction and shaving, of course, will be utilized in the treatment planning only when the actual patient teeth are to be extracted and/or shaved prior to initiating repositioning according to the methods of the present invention.

Removing unwanted and/or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and instructs the software to erase the unwanted section, all triangles within the box set by the user will be removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of the box. The holes created in the model at the faces of the box are re-triangulated and closed using the newly created vertices.

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the tooth or other component images independent of remaining portions of the model. The saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes. A set of lines connects the two curves and shows the user the general cutting path. The user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However, the user may want to make a thicker cut, for example, when shaving down surrounding teeth, as described above. Graphically, the cut appears as the curve bounded by half the thickness of the cut on each side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear

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approximation of the Saw Tool=s curve path. The user chooses the number of erasers, which determines the sophistication of the curve created—the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline curves. Once a saw cut has been completely specified the user applies the cut to the model. The cut is performed as a sequence of erasings. A preferred algorithm is set forth in FIG. 4. FIG. 4A shows a single erasing iteration of the cut as described in the algorithm.

A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

After the user has completed all desired cutting operations with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components. The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. The algorithm is described in FIG. 5.

After the teeth and other components have been placed or removed so that the final tooth arrangement has been produced, it is necessary to generate a treatment plan, as illustrated in FIG. 6. The treatment plan will ultimately produce the series of INTDDS's and FDSS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes. For example, it may be desirable to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit the tooth to be manipulated in a manner that requires the anchor, e.g., lifted relative to the jaw.

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous structure in order to permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances. The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches

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that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path as well as the teeth and other components.

In the manufacturing process, which relies on generation of positive models to produce the repositioning appliance, adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and the appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been added to the mold. When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which engages an anchor placed on the teeth in order to move the tooth in directions which could not otherwise be accomplished.

In addition to such wax patches, an individual component, usually a tooth, can be scaled to a smaller or larger size which will result in a manufactured appliance having a tighter or looser fit, respectively.

Treatment planning is extremely flexible in defining the movement of teeth and other components. The user may change the number of treatment stages, as well as individually control the path and speed of components.

Number of Treatment Stages: The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

Key frames: The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). Unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the initial position, all key frame positions, and the target position). For example, if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position. If the user specifies two key frames for that component, it will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, possibly in yet a different direction, linearly to the target position.

The user can also specify non-linear interpolation between the key frames. A spline curve is used to specify the interpolating function in a conventional manner.

These operations may be done independently to each component, so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between stages 3 and 8, while another moves linearly from stage 1 to 5, and then changes direction suddenly and slows down along a linear path to stage 10. This flexibility allows a great deal of freedom in planning a patient's treatment.

Lastly, the software may incorporate and the user may at any point use a "movie" feature to automatically animate the movement from initial to target states. This is helpful for

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visualizing overall component movement throughout the treatment process.

Above it was described that the preferred user interface for component identification is a three dimensional interactive GUI. A three-dimensional GUI is also preferred for component manipulation. Such an interface provides the treating professional or user with instant and visual interaction with the digital model components. It is preferred over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular segment. In other words, a GUI adapted for manipulation is preferred over an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots. Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

The software also allows for adding annotations to the datasets which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e. it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in FIG. 7. Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from

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Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

After production, the plurality of appliances which comprise the system of the present invention are preferably supplied to the treating professional all at one time. The 10 appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

providing a computer system;
providing to the computer system an initial digital data set representing an initial tooth arrangement;
defining boundaries about at least some of the individual teeth on a visual image provided by the computer system based on the initial data set;
moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce a final data set; and
producing using the computer system a plurality of successive digital data sets based on both of the previously provided initial and final digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing 45 from the initial tooth arrangement to the final tooth arrangement.

2. A method as in claim 1, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's 50 teeth.

3. A method as in claim 1, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

4. A method as in claim 3, wherein the interpolating step comprises linear interpolation.

5. A method as in claim 3, wherein the interpolating step comprises non-linear interpolation.

6. A method as in claim 3, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

7. A method for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial to a final arrangement, said method comprising:

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providing a computer system;
providing to the computer system digital data set representing an initial tooth arrangement;
providing to the computer system a digital data set representing a final tooth arrangement;
interpolating positional differences between the teeth in the initial and final data sets using the computer system to produce a plurality of successive digital data sets, wherein said plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

8. A method as in claim 7, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

9. A method as in claim 7, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and

moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

10. A method as in claim 7, wherein the interpolating step comprises linear interpolation.

11. A method as in claim 7, wherein the interpolating step comprises non-linear interpolation.

12. A method as in claim 7, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

13. A method for fabricating a plurality of dental incremental position adjustment appliances, said method comprising:

providing a digital data set representing an initial tooth arrangement;

providing a digital data set representing a final tooth arrangement;

producing a plurality of successive digital data sets based on the previously provided digital data sets, wherein said plurality of digital data sets represent a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement; controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the successive tooth arrangements; and

producing the dental appliance as a negative of the positive model.

14. A method as in claim 13, wherein the step of providing a digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

15. A method as in claim 13, wherein the step of providing a digital data set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth; and

moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the final data set.

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16. A method as in claim 13, wherein the step of producing a plurality of successive digital data sets comprises determining positional differences between the initial data set and the final data set and interpolating said differences.

17. A method as in claim 16, wherein the interpolating step comprises linear interpolation.

18. A method as in claim 16, wherein the interpolating step comprises non-linear interpolation.

19. A method as in claim 16, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

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20. A method as in claim 13, wherein the controlling step comprises:

providing a volume of non-hardened polymeric resin; and scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

21. A method as in claim 13, wherein the producing step comprises modeling the appliance over the positive model.

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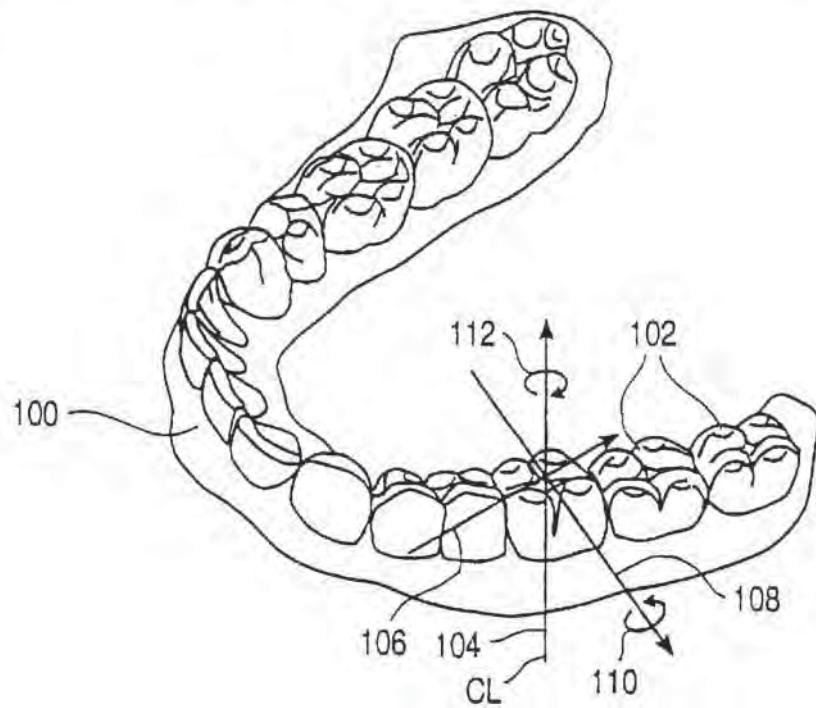


FIG. 1A

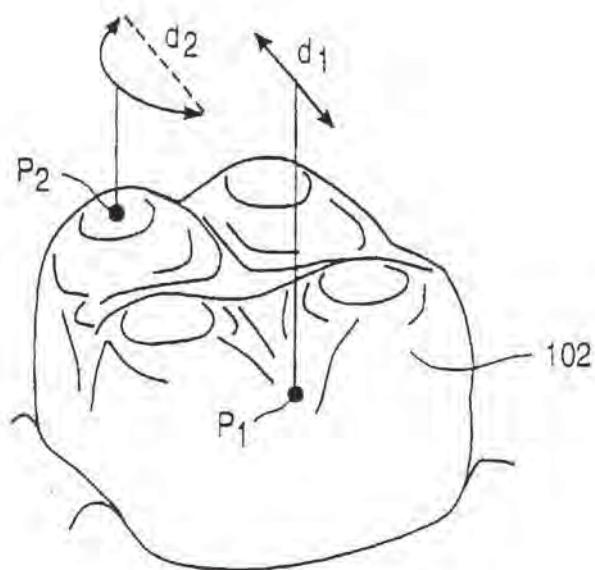


FIG. 1B

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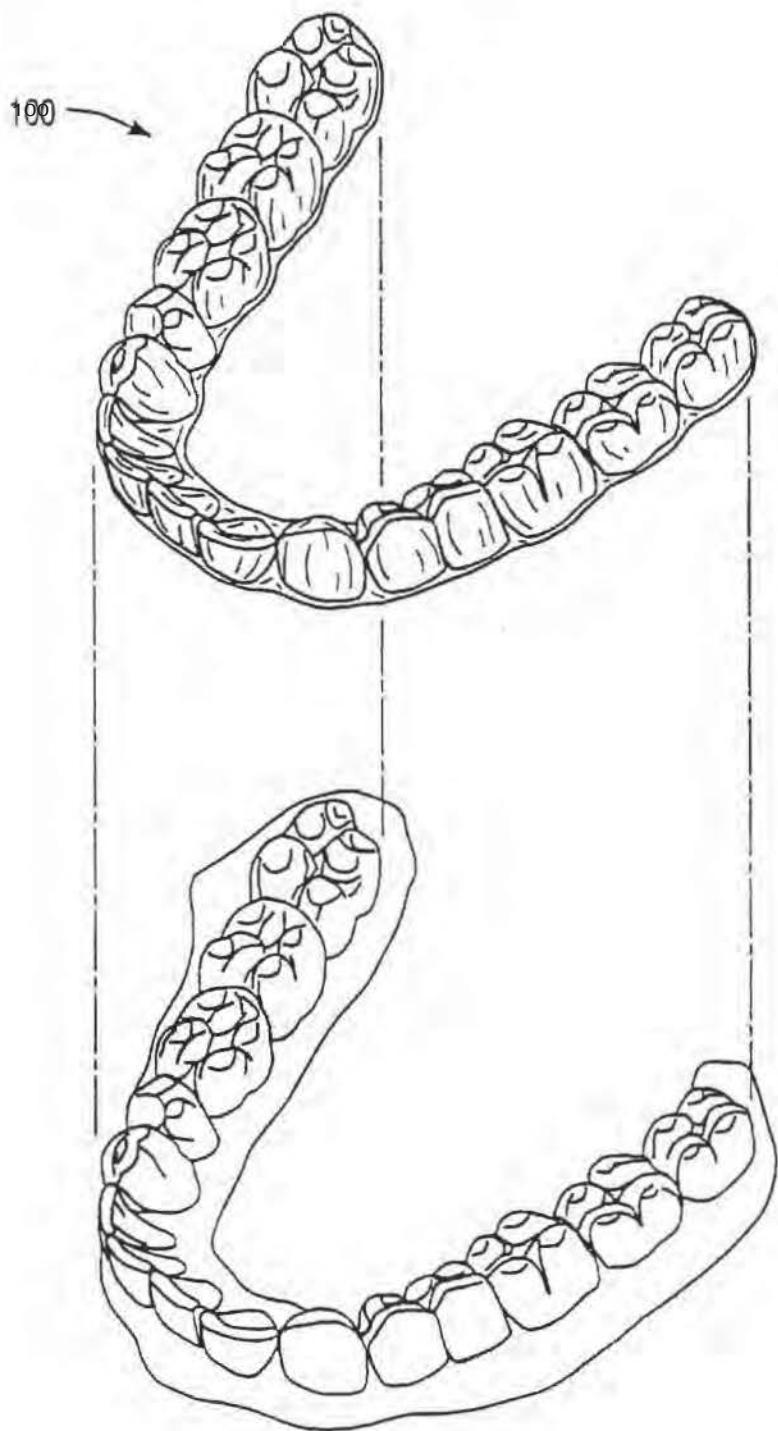


FIG. 10

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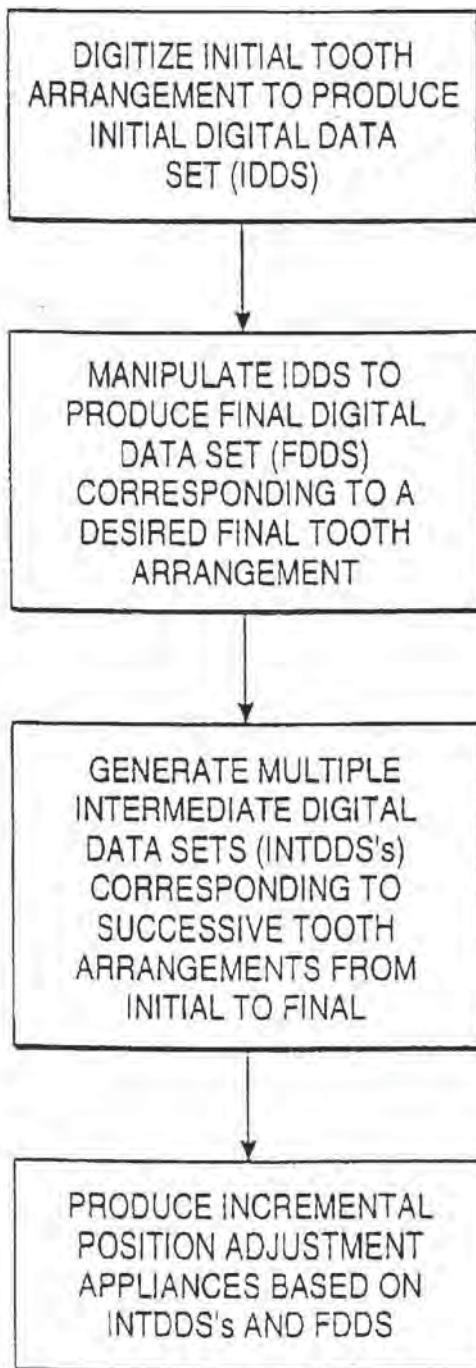
CROSS-REFERENCE
FIG. 3CROSS-REFERENCE
FIG. 6

FIG. 2

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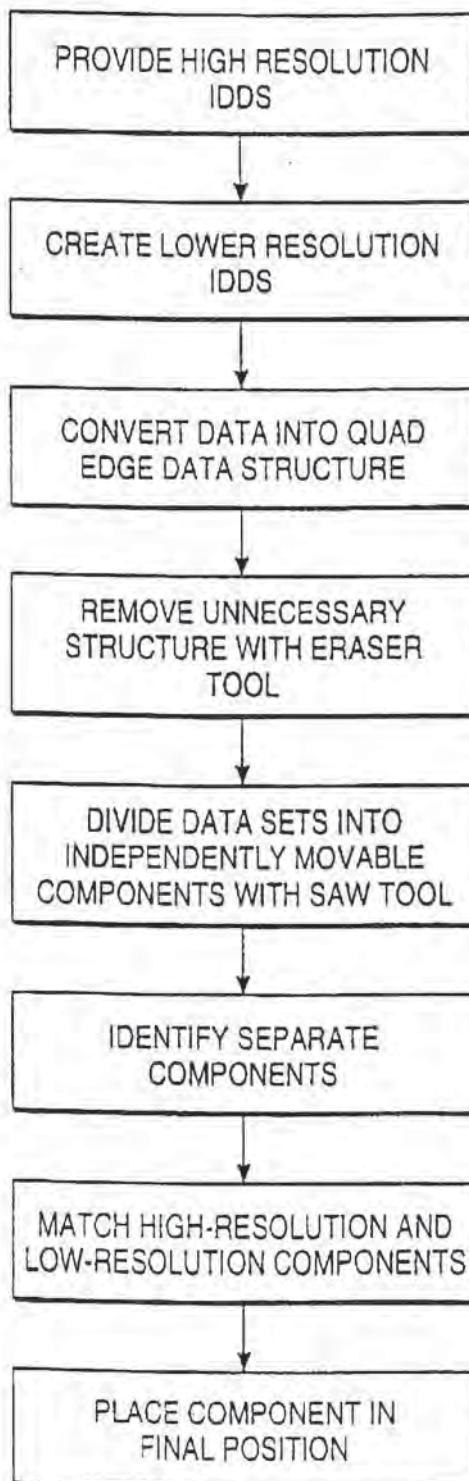
CROSS-REFERENCE
FIG. 4CROSS-REFERENCE
FIG. 5

FIG. 3

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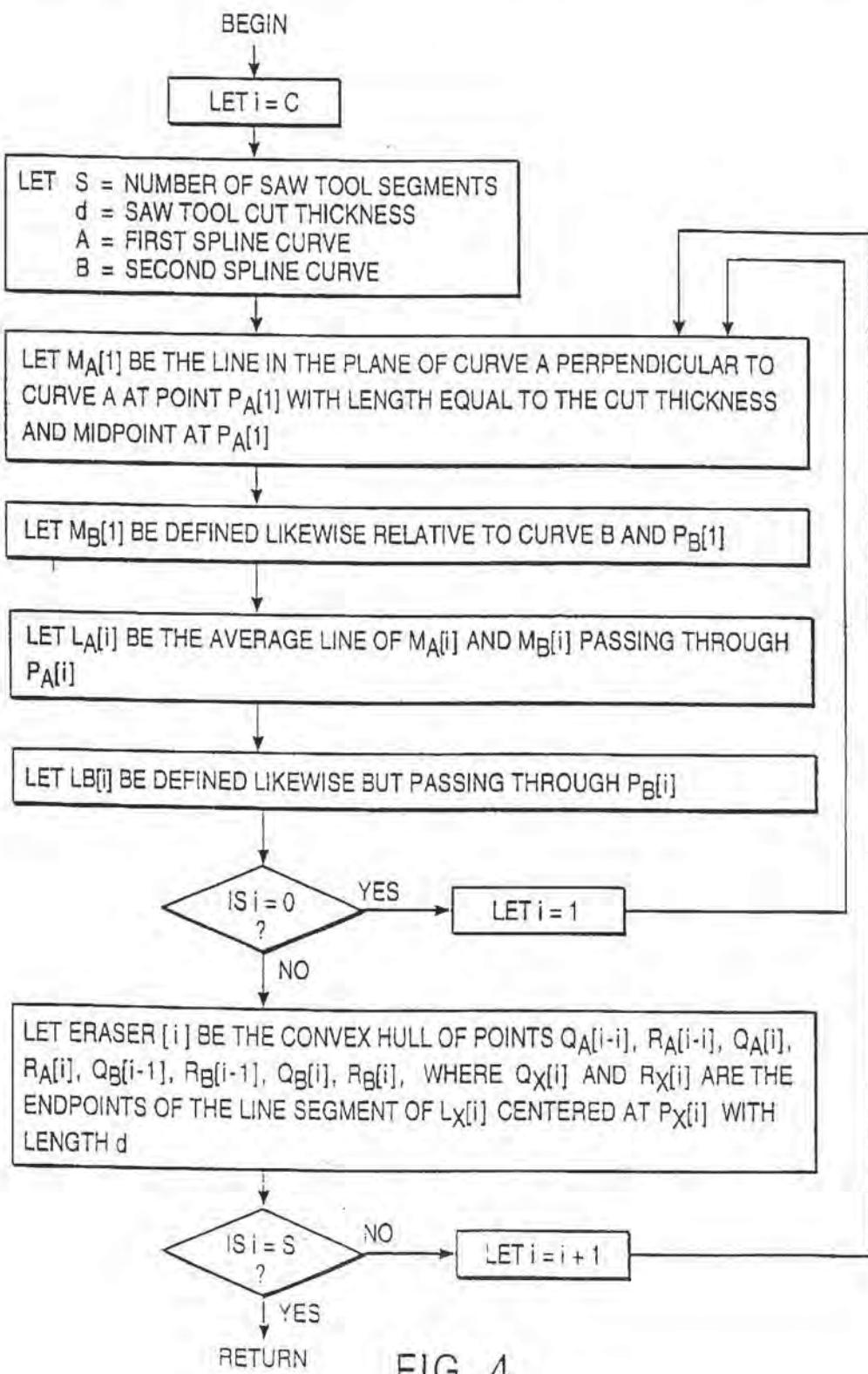


FIG. 4

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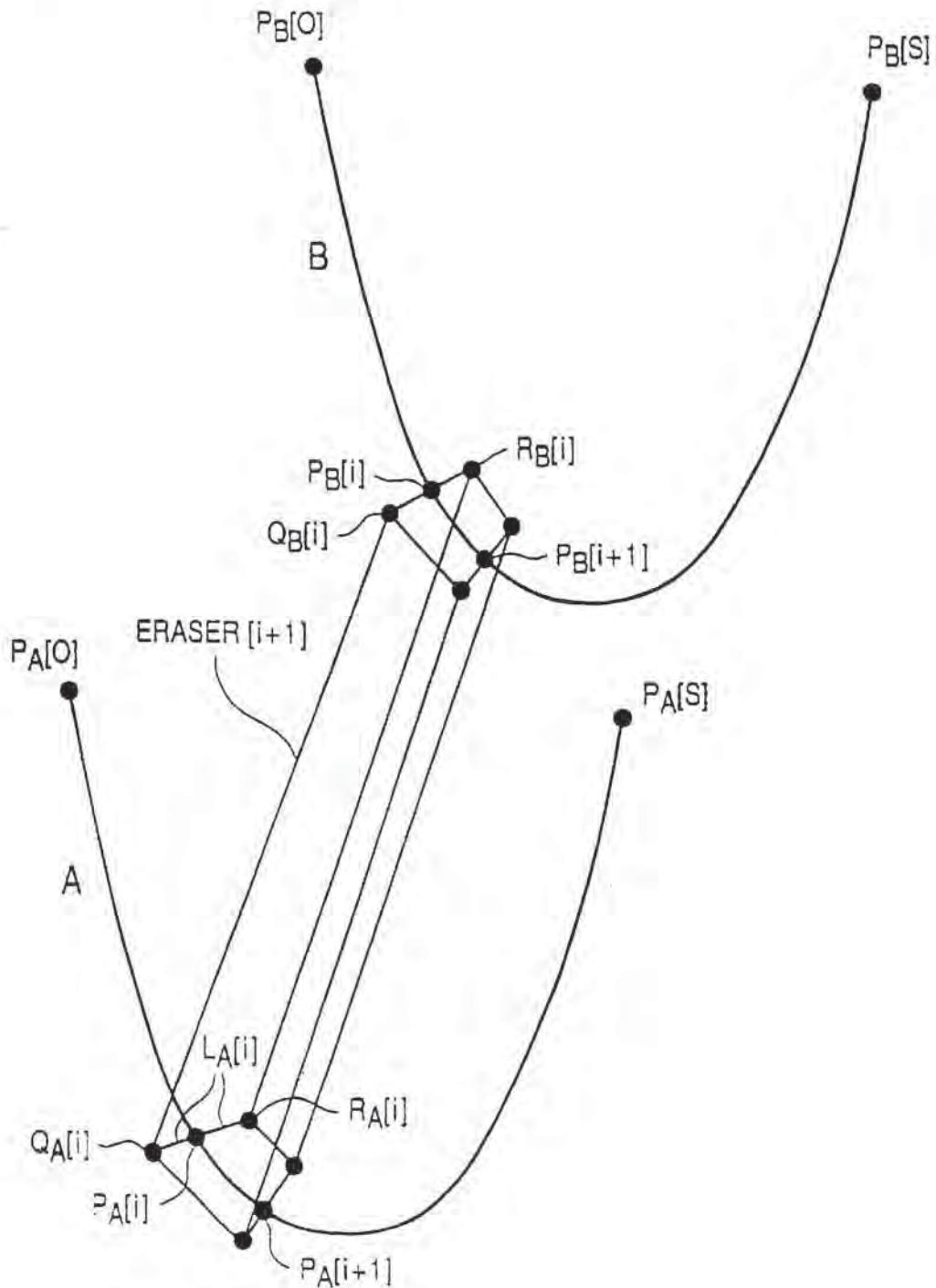


FIG. 4A

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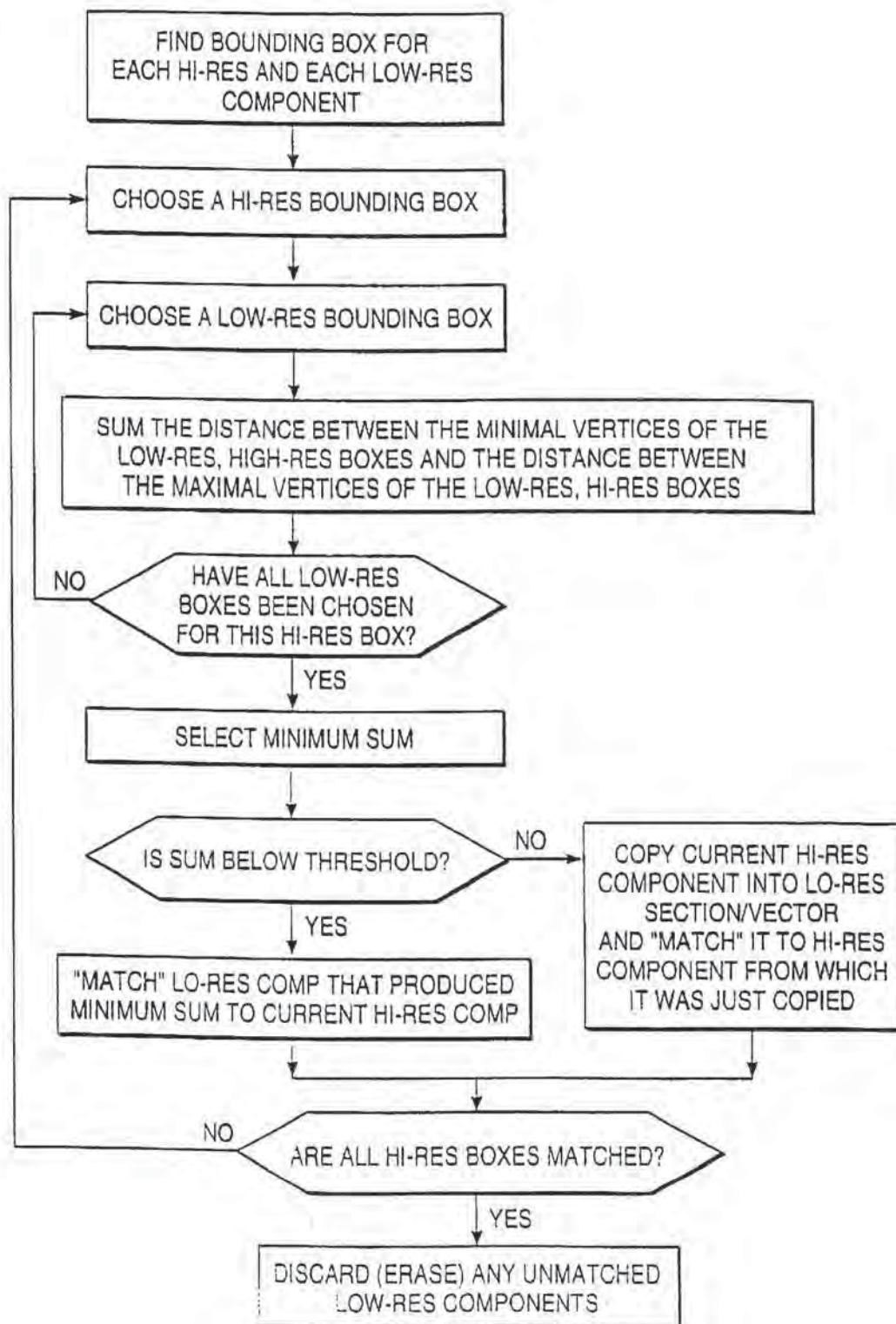


FIG. 5

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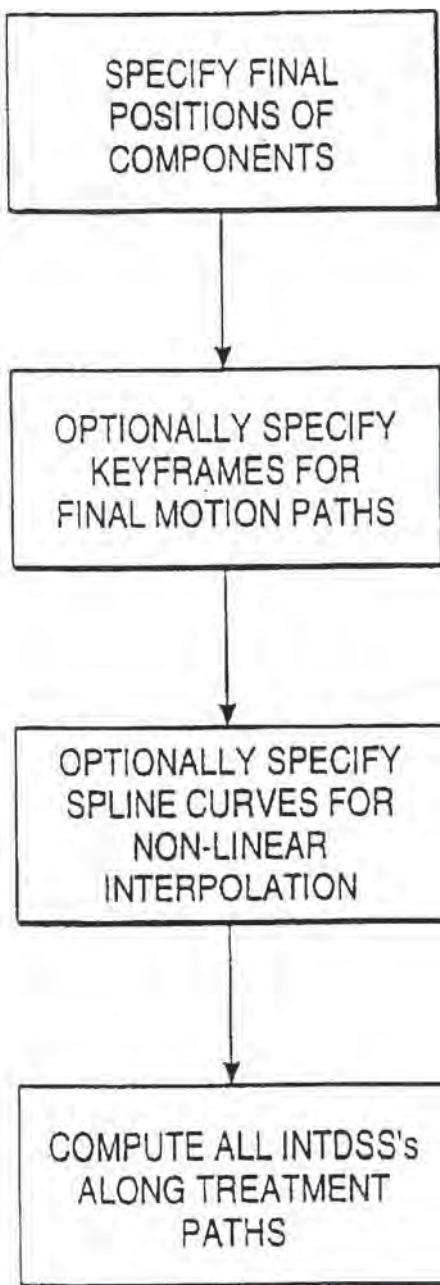


FIG. 6

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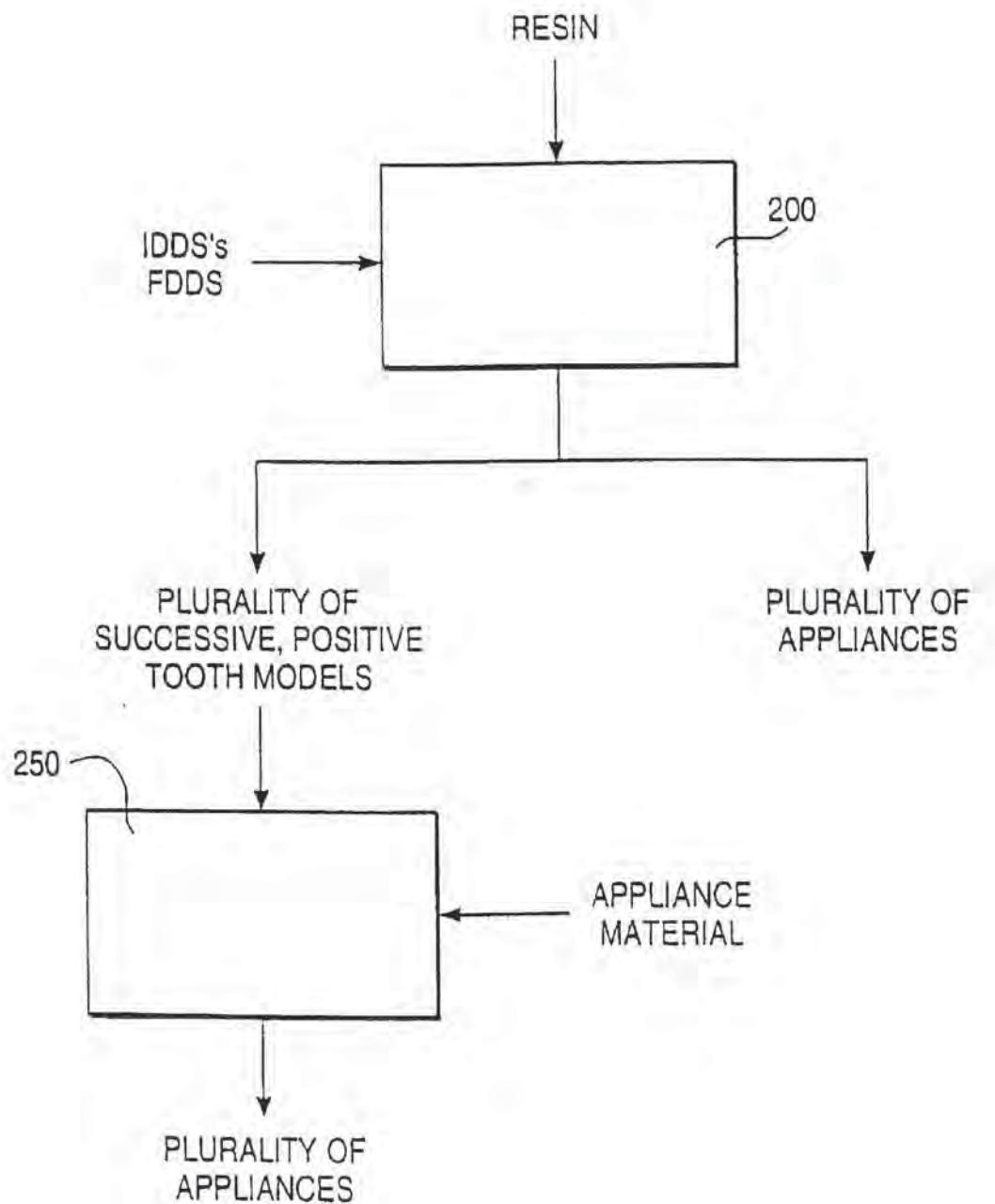
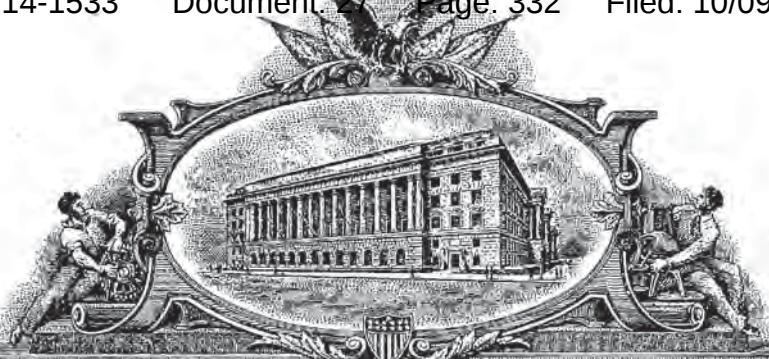


FIG. 7

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December 21, 2011

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THIS OFFICE OF:

U.S. PATENT: 6,705,863
ISSUE DATE: March 16, 2004

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office


M. K. CARTER
Certifying Officer





US006705863B2

(12) **United States Patent**
Phan et al.

(10) Patent No.: US 6,705,863 B2
(45) Date of Patent: *Mar. 16, 2004

(54) ATTACHMENT DEVICES AND METHODS FOR A DENTAL APPLIANCE

(75) Inventors: Loc X. Phan, Milpitas, CA (US); Muhammad Z. Chishti, Sunnyvale, CA (US); Ross J. Miller, Sunnyvale, CA (US)

(73) Assignee: Align Technology, Inc., Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 281 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 10/040,269

(22) Filed: Oct. 29, 2001

(65) Prior Publication Data

US 2002/0106604 A1 Aug. 8, 2002

Related U.S. Application Data

- (63) Continuation-in-part of application No. 09/454,278, filed on Dec. 3, 1999, now Pat. No. 6,309,215, which is a continuation-in-part of application No. 09/466,353, filed on Dec. 17, 1999, now Pat. No. 6,398,548, which is a continuation of application No. PCT/US98/12861, filed on Jun. 19, 1998, which is a continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893, which is a continuation-in-part of application No. 09/250,962, filed on Feb. 16, 1999, now Pat. No. 6,183,248, which is a continuation-in-part of application No. 09/169,034, filed on Oct. 8, 1998, now Pat. No. 6,471,511, which is a continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.
(60) Provisional application No. 60/110,881, filed on Dec. 4, 1998, provisional application No. 60/050,342, filed on Jun. 20, 1997, provisional application No. 60/110,189, filed on Nov. 30, 1999, and provisional application No. 60/050,342.
(51) Int. Cl.⁷ A61L 13/00
(52) U.S. Cl. 433/24; 433/6
(58) Field of Search 433/6, 24

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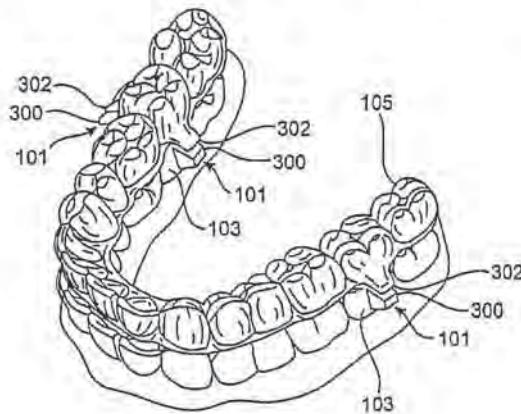
Primary Examiner—Cary E. O'Connor

(74) Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP; Bao Tran, Esq.

(57) ABSTRACT

The present invention provides improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment. These appliances function by applying force to specific surfaces of the teeth or dental features to cause directed movement. The application of force is improved by the use of one or more attachment devices which may be positioned on the teeth or dental features to provide the appropriate physical features. Specific design and location of these attachment devices may provide newly achievable and/or more effective repositioning forces, anchoring ability and appliance retention. The systems and methods of the present invention provide the design, production and use of such attachment devices with removable dental positioning appliances in orthodontic treatment.

20 Claims, 14 Drawing Sheets



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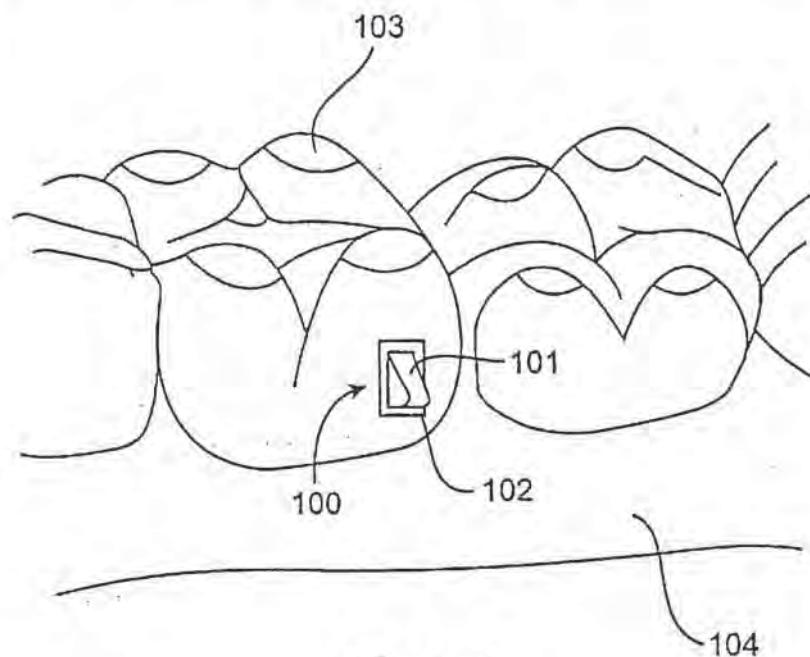


FIG. 1

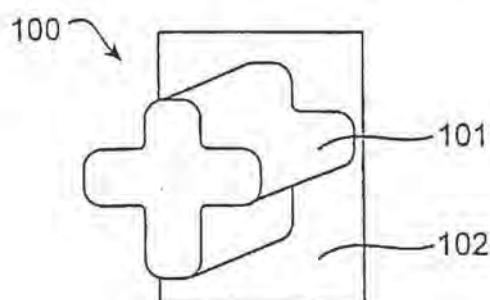


FIG. 2A

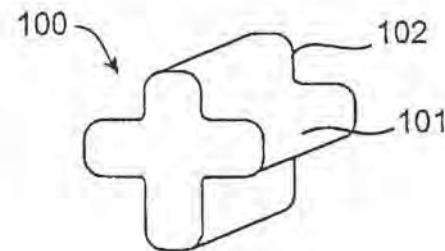


FIG. 3A

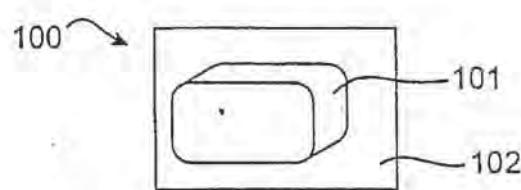


FIG. 2B

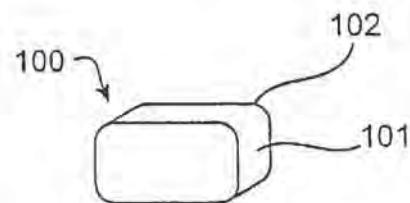


FIG. 3B

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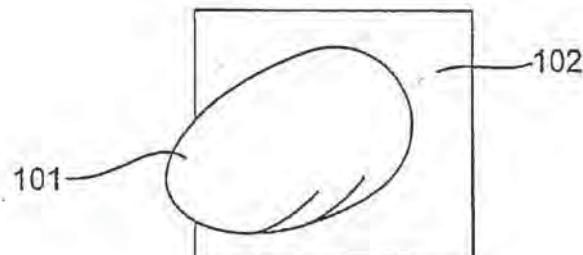


FIG. 4B

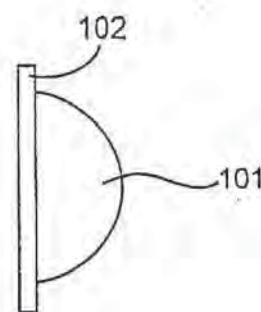


FIG. 4A

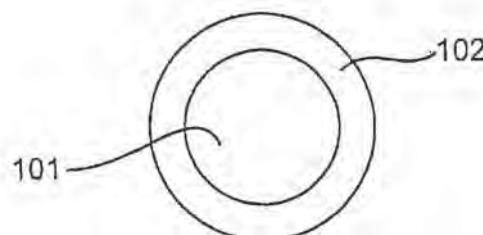


FIG. 4

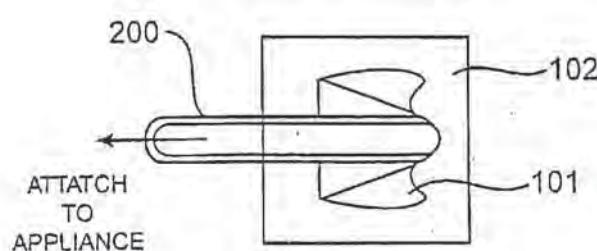


FIG. 5

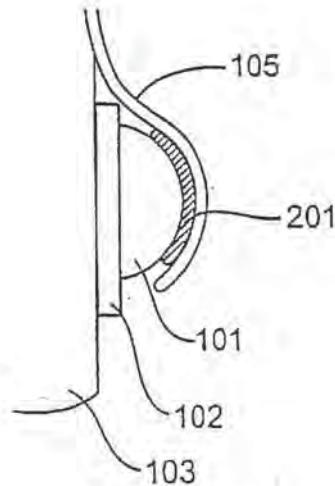


FIG. 6

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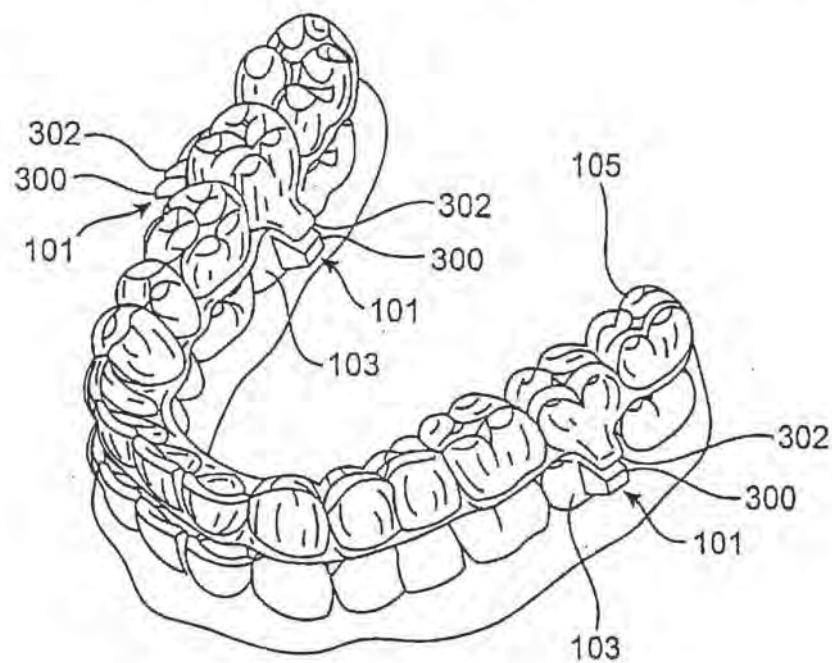


FIG. 7

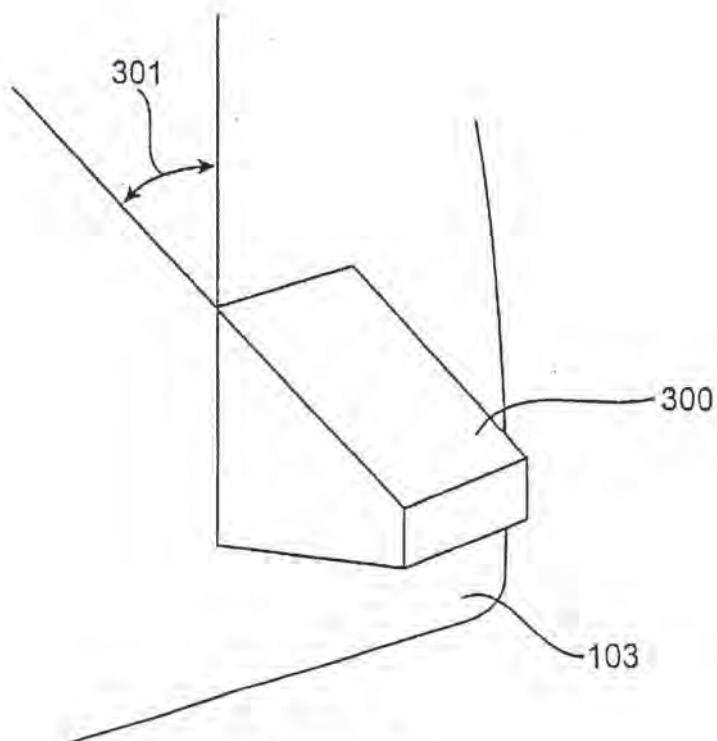


FIG. 8

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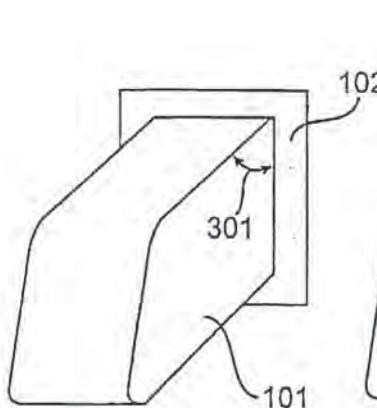


FIG. 9A

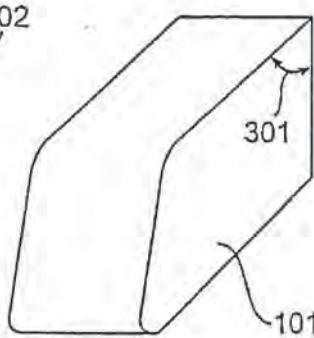


FIG. 9B

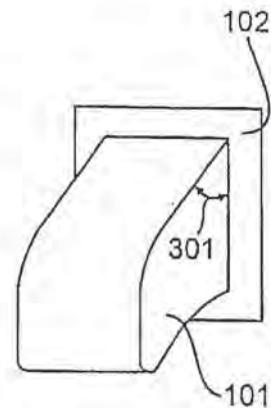


FIG. 9C

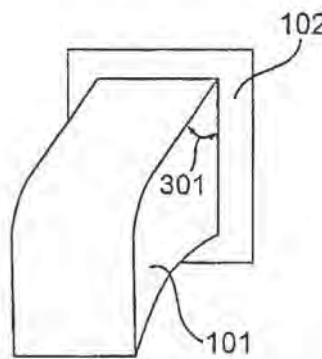


FIG. 9D

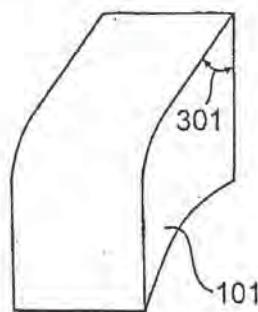


FIG. 9E

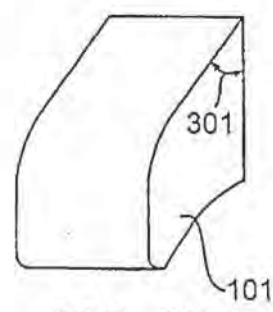


FIG. 9F

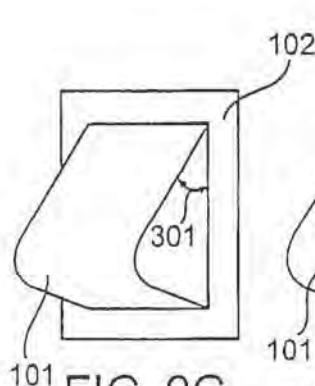


FIG. 9G

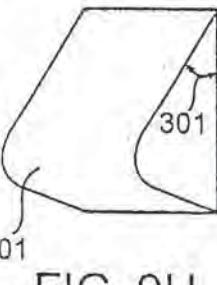


FIG. 9H

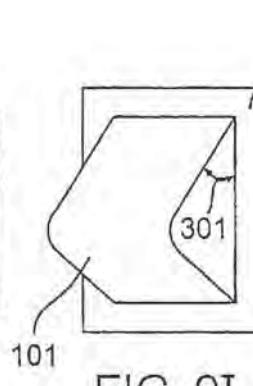


FIG. 9I

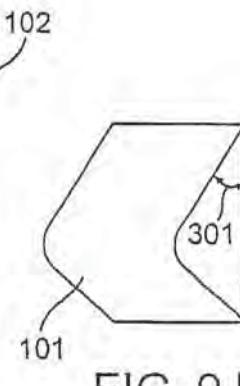


FIG. 9J

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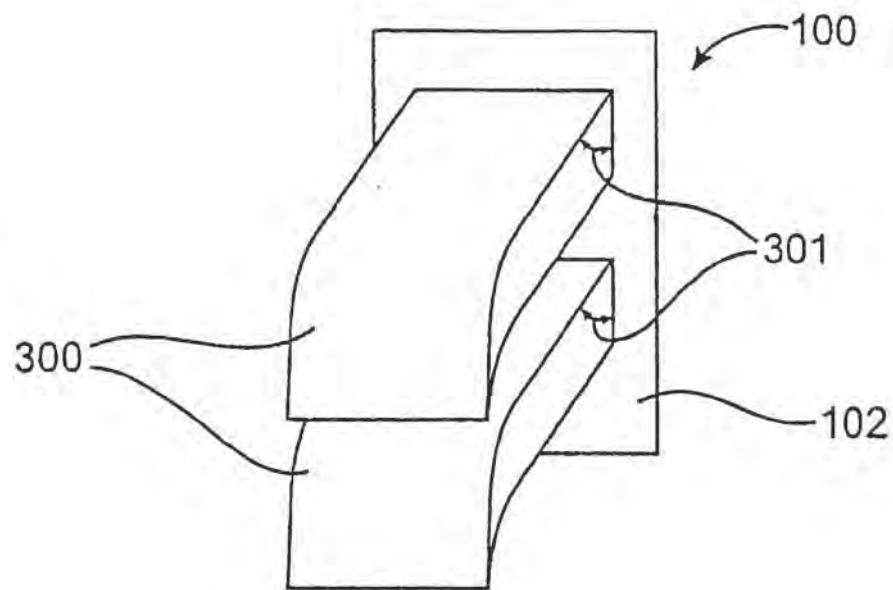


FIG 9K

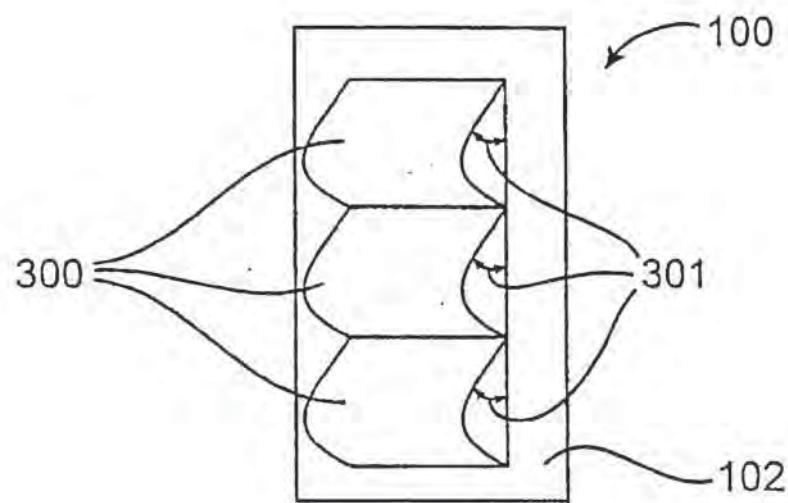


FIG 9L

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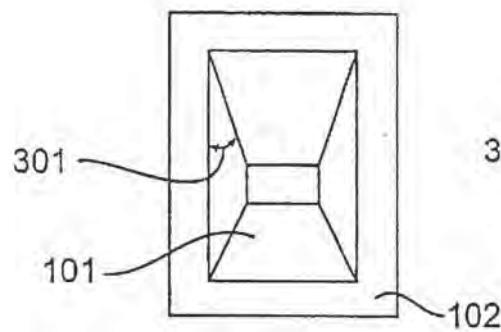


FIG. 10A

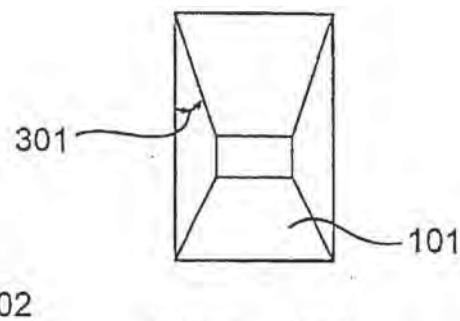


FIG. 10B

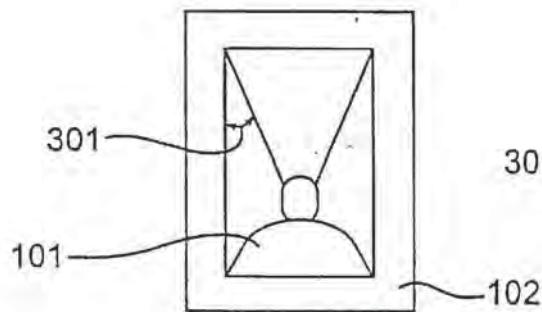


FIG. 10C

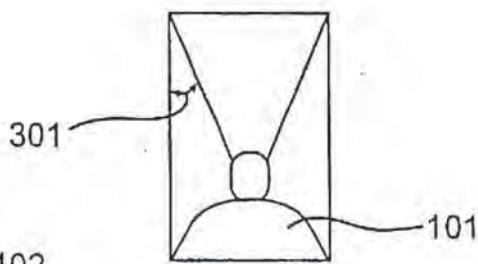


FIG. 10D

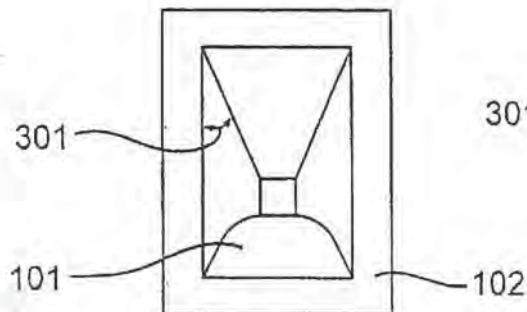


FIG. 10E

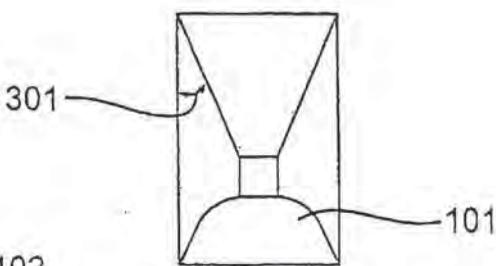


FIG. 10F

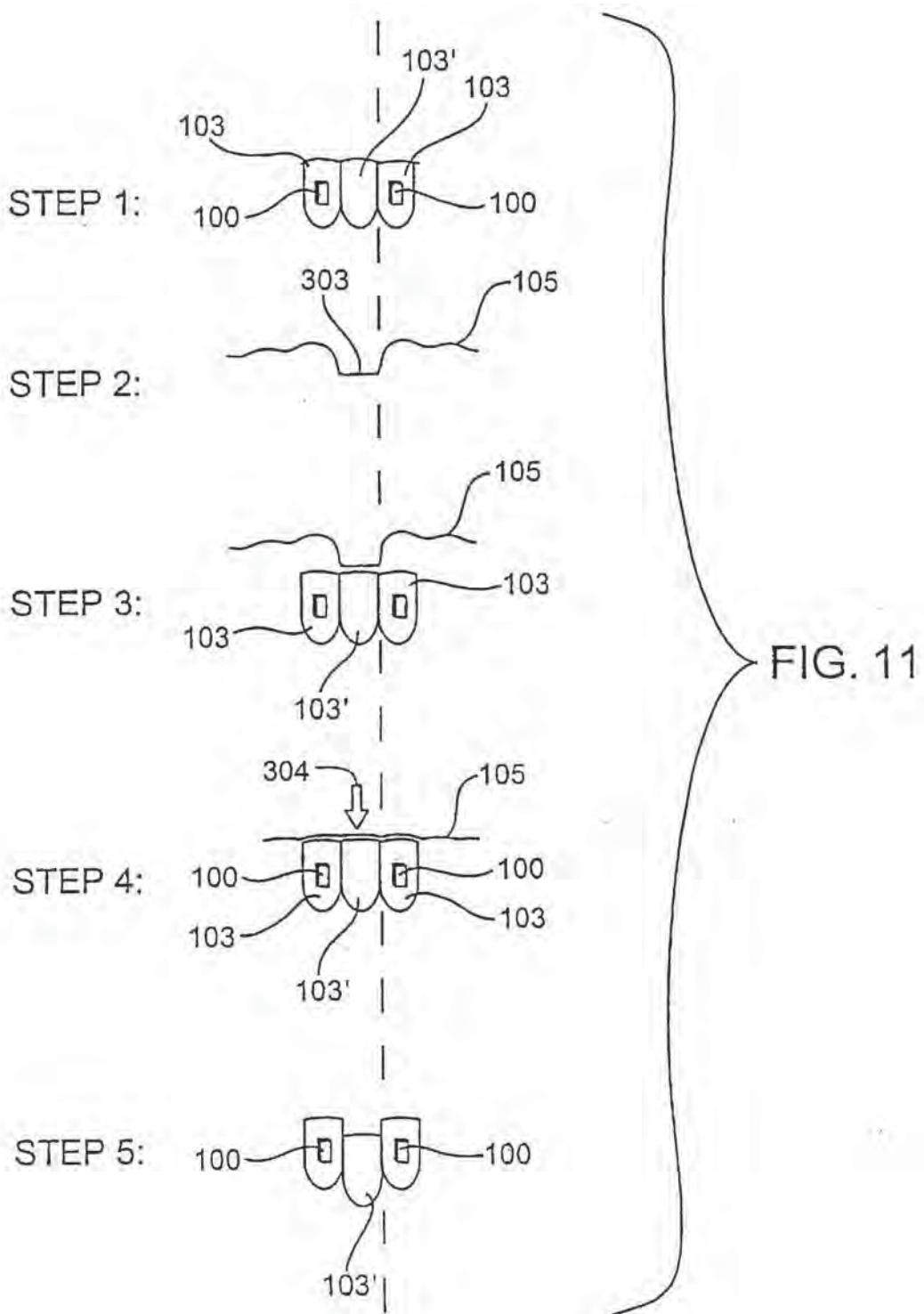
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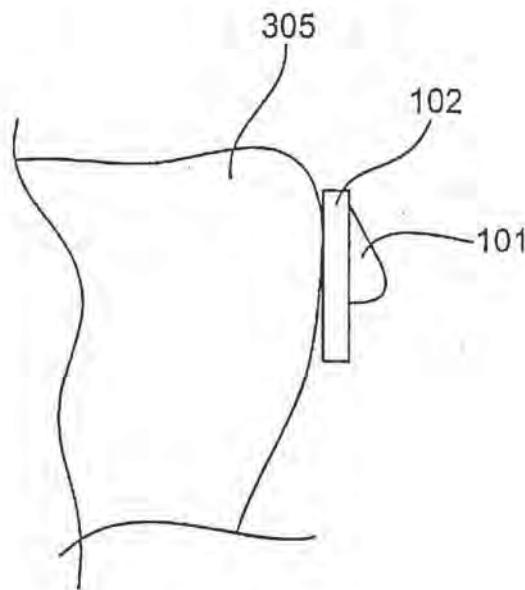


FIG. 12A

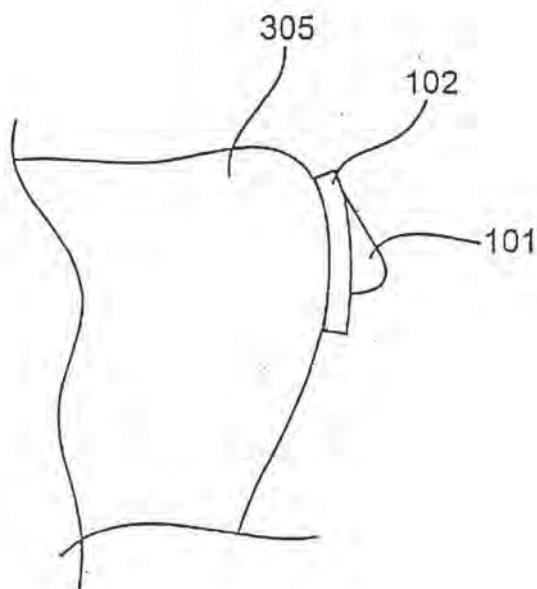


FIG. 12B

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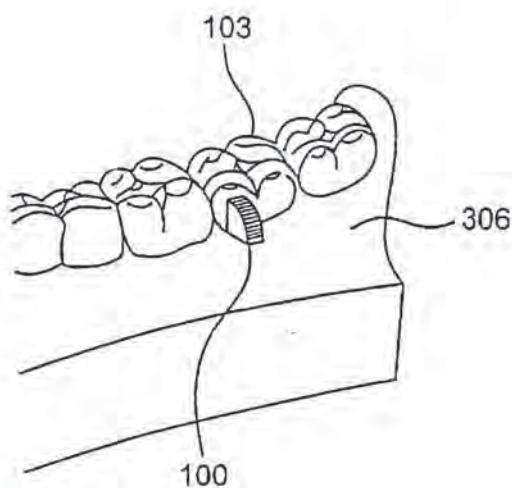


FIG. 13A

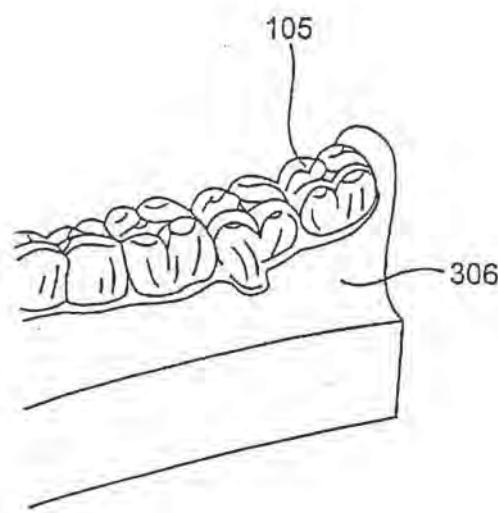


FIG. 13B

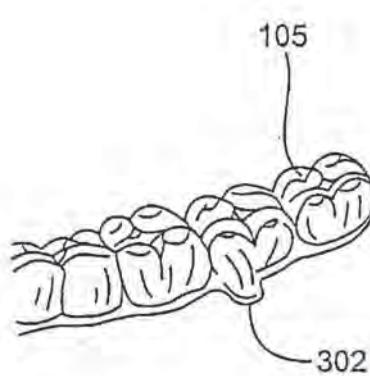


FIG. 13C

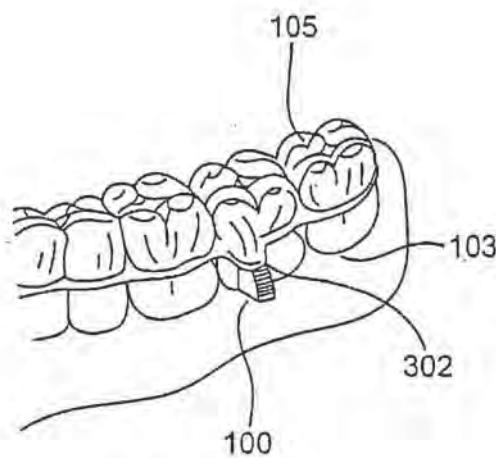


FIG. 13D

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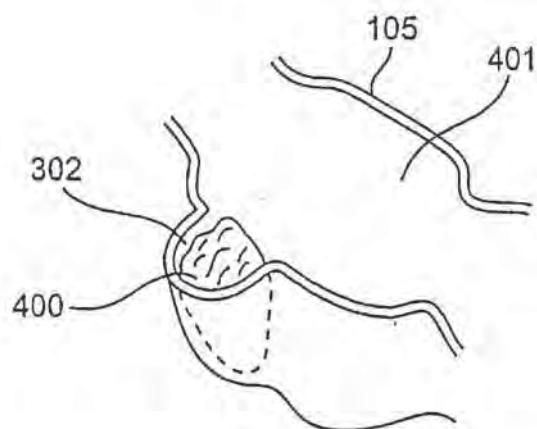


FIG. 14A

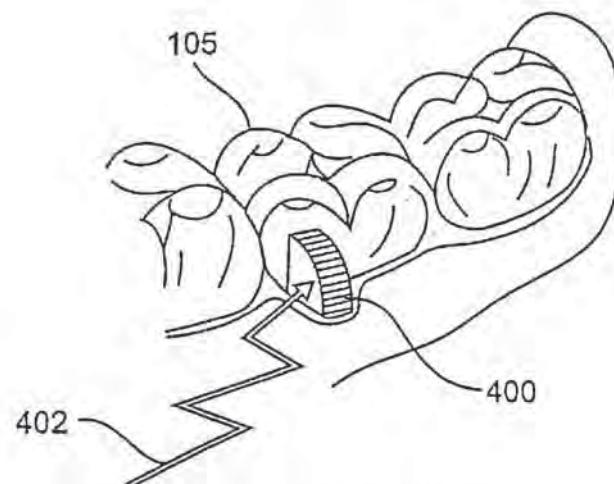


FIG. 14B

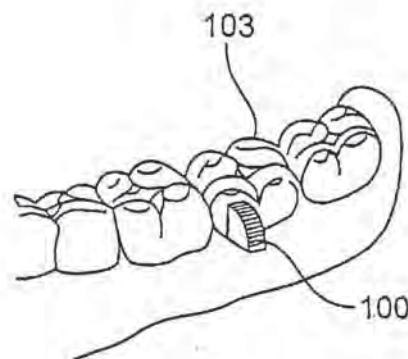


FIG. 14C

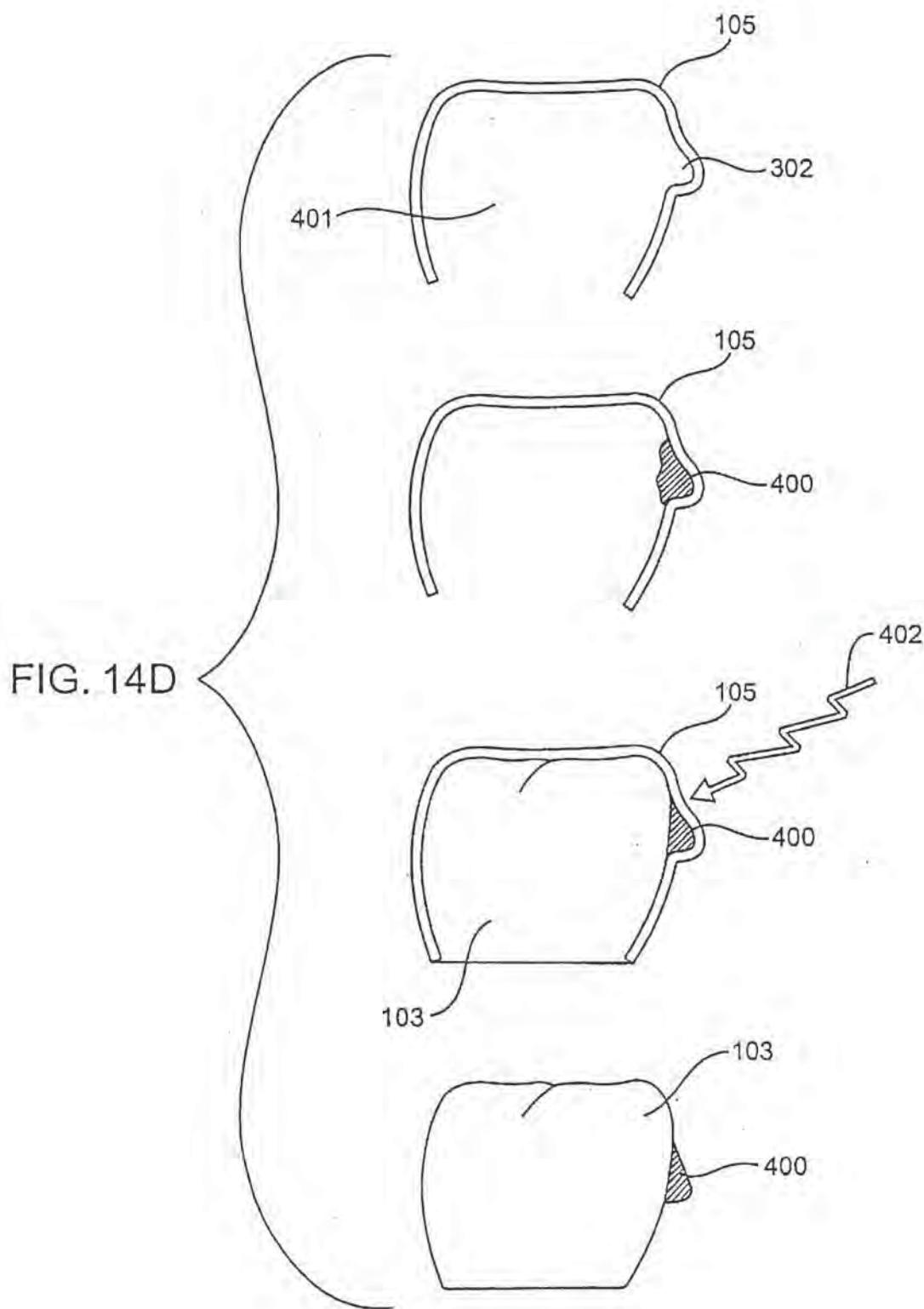
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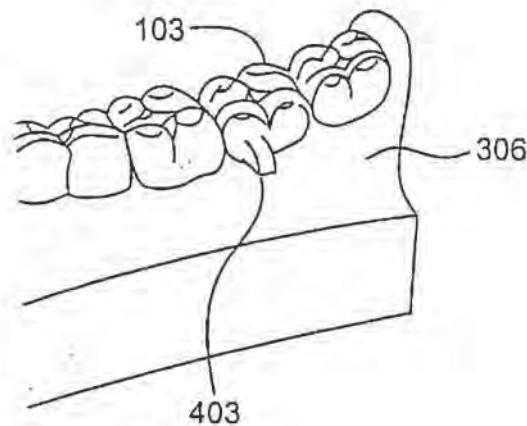


FIG. 15A

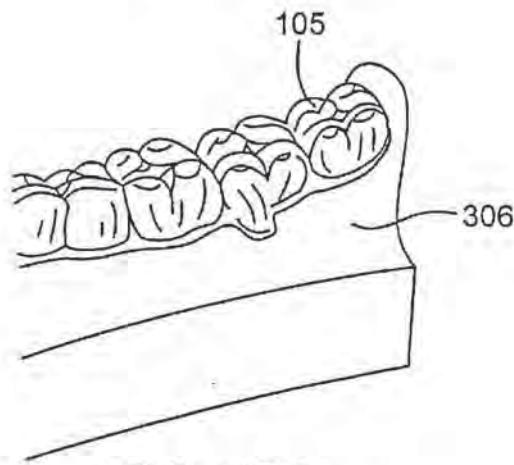


FIG. 15B

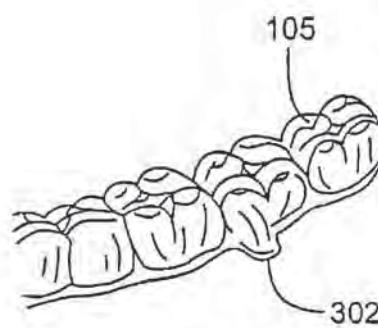


FIG. 15C

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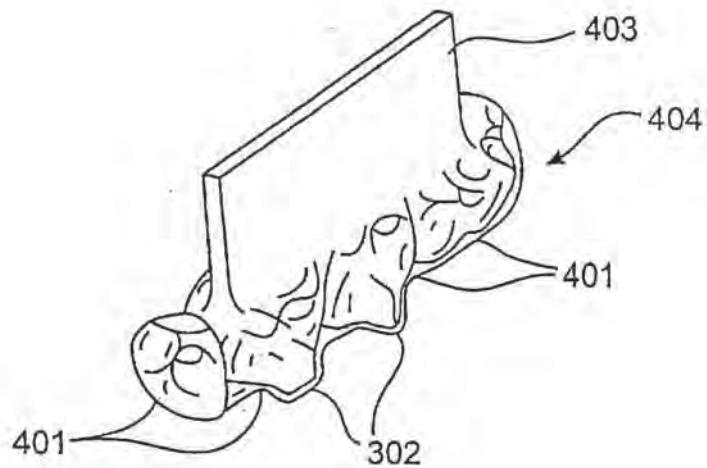


FIG. 16

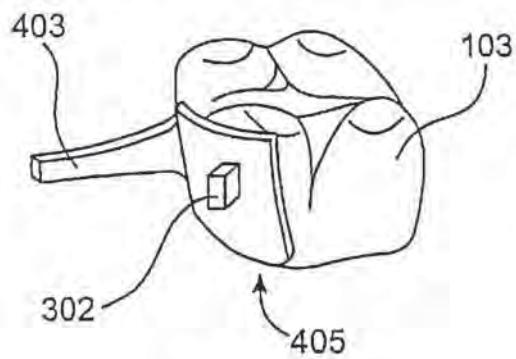


FIG. 17A

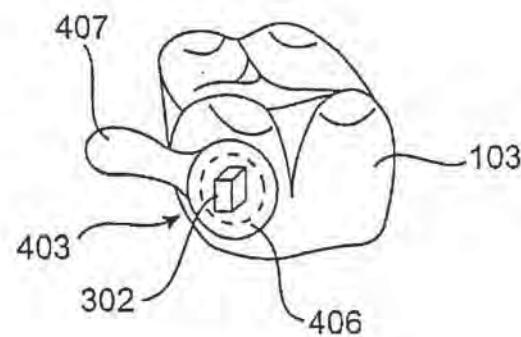


FIG. 17B

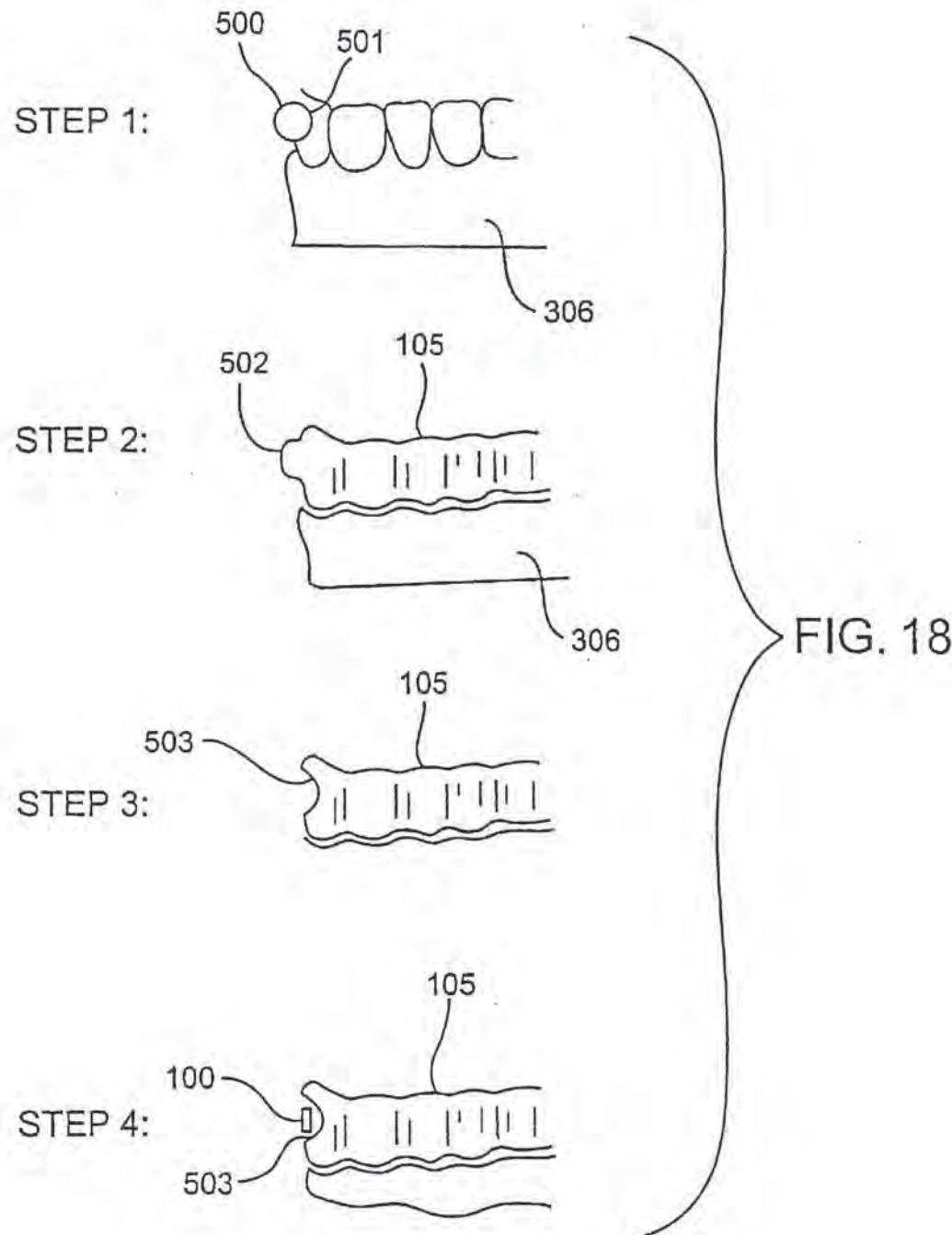
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ATTACHMENT DEVICES AND METHODS FOR A DENTAL APPLIANCE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 09/454,278, filed Dec. 3, 1999 now U.S. Pat. No. 6,309,215, which claimed the benefit of provisional application No. 60/110,881, filed Dec. 4, 1998. This application is also a continuation-in-part of application Ser. No. 09/466,353, now U.S. Pat. No. 6,398,548, filed Dec. 17, 1999, which was a continuation-in-part of PCT/US98/12861, filed Jun. 19, 1998, which was a continuation-in-part of application Ser. No. 08/947,080, filed on Oct. 8, 1997, now U.S. Pat. No. 5,975,893, which claimed the benefit of provisional application No. 60/050,342, filed on Jun. 20, 1997. This application is also a continuation-in-part of application Ser. No. 09/250,962, filed on Feb. 16, 1999, now U.S. Pat. No. 6,183,248, which claimed the benefit of provisional application No. 60/110,189, filed on Nov. 30, 1999. This application is also a continuation-in-part of application Ser. No. 09/169,034, filed on Oct. 8, 1998 now U.S. Pat. No. 6,471,511, which was a continuation-in-part of application Ser. No. 08/947,080, filed on Oct. 8, 1997, now U.S. Pat. No. 5,975,893, which claimed the benefit of provisional application No. 60/050,342, filed on Jun. 20, 1997. The full disclosures of each of these applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment.

Orthodontic treatments involve repositioning misaligned teeth and improving bite configurations for improved cosmetic appearance and dental function. Repositioning teeth is accomplished by applying controlled forces to the teeth over an extended period of time. This is conventionally accomplished by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, bands, archwires, ligatures, and O-rings. The brackets and bands are bonded to the patient's teeth using a suitable material, such as dental adhesive. Once the adhesive has set, the archwire is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontics as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted. This involves installing different archwires having different force-inducing properties or by replacing or tightening existing ligatures. Between meetings, the patient may be required to wear supplementary appliances, such as elastic bands or headgear, to supply additional or extraoral forces.

Although conventional braces are effective, they are often a tedious and time consuming process requiring many visits to the orthodontist's office. Moreover, from a patient's perspective, they are unsightly and uncomfortable.

Moreover, the archwire and ligatures which connect the brackets in a continuous network make brushing, flossing between the teeth and other dental hygiene procedures difficult, possibly contributing to the development of gingivitis. Consequently, alternative orthodontic treatments are needed. In particular, it would be desirable to use appliances which can be removed by the patient during daily dental hygiene routines, while participating in athletic activities, or for cosmetic purposes.

A particularly promising approach relies on the use of elastic positioning appliances for realigning teeth. Such appliances comprise a thin shell of elastic material that generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled forces in specific locations to gradually move the teeth into the new configuration. Repetition of this process with successive appliances comprising new configurations eventually move the teeth through a series of intermediate configurations to a final desired configuration. A full description of an exemplary elastic polymeric positioning appliance is described in U.S. Pat. No. 5,975,893, and in published PCT application WO 98/58596 which designates the United States and which is assigned to the assignee of the present invention. Both documents are incorporated by reference for all purposes.

In addition to their ease of use, polymeric positioning appliances are generally transparent, providing an improved cosmetic appearance, and impart substantial force on the teeth, due to stiffness of the appliance. The stiffness of an elastic positioning appliance is a result of the modulus of the thermoformable polymer materials from which it is made. The higher the modulus of the materials, the higher the stiffness of the appliance. When a patient positions such an appliance over a prescribed group of teeth, one or more of the teeth will provide a base or anchor region for holding the positioning appliance in place while the stiffness of the polymeric material will impart a resilient repositioning force against one or a portion of the remaining teeth. By designing the appliance to cover the teeth, a much larger contact surface area is afforded compared to traditional spring retainers and wire-based appliances. However, such anchoring and repositioning abilities of removable elastic positioning appliances are still dependent on the physical features and configuration of the patient's teeth, palette, and previous dental work, to name a few. For example, shell-like elastic polymeric positioning appliances have difficulty applying certain forces to individual teeth, such as extrusive force (e.g., pulling or raising a tooth relative to the jaw).

Thus, it would be desirable to provide tooth positioners, systems, and methods which apply adequate force in desired directions to selected teeth at specific times during treatment. In particular, it would be desirable to enable the fabrication and use of removable positioners and systems which can apply extrusive, rotational, and other directional forces which have heretofore been difficult to apply with removable positioners. It would also be desirable to reduce the cost of the orthodontic treatment and retain the patient benefits of a removable appliance in cases where they might not otherwise be available. At least some of these objectives will be met by the designs and methods of the present invention described hereinafter.

SUMMARY OF THE INVENTION

The present invention provides improved devices, systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during

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orthodontic treatment. Such removable dental positioning appliances usually comprise an elastic polymeric shell having a cavity for receiving at least some of a patient's teeth and are often preferred over conventional braces for tooth repositioning due to comfort, appearance and ease of use. These appliances function by applying force to specific surfaces of the teeth or dental features to cause directed movement. However, the type of movement and level of force applied is usually dependent on the surface characteristics and positions of the dental features. In many cases, the native tooth surface(s) and other dental features of a patient are inadequate to provide sufficient anchoring or to impart sufficient force on the teeth to be repositioned. To overcome these limitations, the present invention uses one or more attachment devices which may be attached to preselected attachment points on the teeth or dental features to provide the appropriate physical leverage. Specific design and location of these attachment devices may provide newly achievable and/or more effective repositioning forces, anchoring ability and appliance retention. The systems and methods of the present invention provide the design, production and use of such attachment devices with removable dental positioning appliances in orthodontic treatment.

The use of attachment devices in combination with removable dental positioning appliances provides the patient with the benefits of removable appliances while retaining the ability to extrude, rotate, and otherwise manipulate teeth as with conventional braces. Like conventional braces, attachment devices may be bonded to the surface of the teeth in order to provide physical features which facilitate the application of controlled force. The attachment devices of the present invention may have a very simple construction, in some instances being only a bump, bead, wedge, or other body or structure which can be fixedly attached to the surface of a tooth or other dental feature in order to transmit force generated by the dental positioning appliance to the dental feature and/or to anchor the positioning appliance to teeth in order to permit the appliance to apply forces elsewhere in the patient's teeth. In such instances, the attachment device acts simply as a handle or lever to assist in the transmission of force between the teeth and the dental positioning appliance. In other instances, the attachment device may feature a hook, similar in design to those used for mounting elastic bands. The hook may be engaged with a number of ligatures, bands, filaments, coils or other connecting members to effect repositioning of the teeth, usually in combination with the dental positioning appliance. The hook may serve as an anchor in the repositioning of other teeth, or it may serve as a point of purchase to apply directed force to the surface of the tooth to which it is bonded.

The attachment devices of the present invention, unlike conventional braces, are typically small, infrequent, (i.e., present on very few of the patient's teeth) unnoticeable to others, and do not interfere with dental hygiene practices. Usually, the attachment device will have a small base e.g., up to 4 mm across (mesial-distal) and up to 6 mm long (gingiva-crown). An attachment device body may typically protrude up to a maximum of 2.5 mm. This is significantly smaller than standard brackets or bands used in conventional braces which may protrude up to 4 mm. The devices may be bonded in specific locations throughout the dentition where appropriate and this may only be required at one or a few locations. Thus, the infrequency of the device, in addition to the size, also reduces its visibility and awareness to the patient. Likewise, the attachment device may be bonded to any surface of the teeth, including lingual surfaces which

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would allow the devices to be largely unnoticeable to others. In these cases, shape and design considerations would prevent any irritation to the contacting tissues, such as the tongue, inner lip and inner cheek. When placed in visible areas, the attachment device may be color matched to the dental surface to further diminish its visibility. In addition, such attachment devices are typically designed to removably attach to a removable dental appliance. Thus, when the appliance is removed, routine brushing, flossing and dental care may be undertaken in the usual manner.

Brackets used with conventional braces, such as those used to support elastic bands or headgear, are limited in design and therefore application of use. Generally, these attachment devices have a large profile, protruding 2-4 mm, which is not conducive to use with elastic positioning appliances or other devices designed to be removably positioned over the attachment device. Likewise, their surface geometry is limited to a few prescribed functions which are specific to use with conventional braces. Thus, they are not adequately capable of providing functions necessary to the present invention, such as removably attaching a dental positioning appliance.

In a first aspect of the present invention, the attachment devices are comprised of an attachment body having a base. The base may simply be the portion of the attachment body which will be bonded to the surface of the dental feature. Alternatively, the base may be an enlarged portion of the body, designed to increase the surface area of the bond. Likewise, the base may be removable or permanently attached. The attachment body may feature a variety of designs, most commonly being bumps, beads, wedges, also including but not limited to hooks, clasps, bands, brackets, buttons, snaps, springs, levers, rods, tubes, coils, indents and/or other protrusions. Each design may serve one or a number of purposes in repositioning of the teeth. For example, a clasp may be used to attach a portion of a removable positioning appliance to the attachment device. This attachment device design may be desired for anchoring of the appliance or applying force to the dental feature to which the attachment device is bonded. Additional devices may be used in conjunction with the attachment body to attach the appliance to the attachment device. For example, adhesives, flexible bands or connecting ligatures may be used in conjunction with the design of the attachment body to aid in connection to the appliance. In one such case, an attachment body located on the lower jaw may be attached to a removable appliance placed on the upper jaw by means of a flexible band. This may afford desired force vectors that are unobtainable by other means. Alternatively, the attachment body may be comprised of specific design features to aid in properly seating a removable elastic repositioning appliance, in addition to anchoring the appliance in place to apply repositioning forces. A preferred embodiment of these design features includes an attachment body with a sloping face e.g., a wedge.

The phrase "dental feature" will apply to any portion of the patient's teeth which may be contacted by a dental positioning appliance and/or engaged by an attachment device. Usually, the dental feature will be a portion of a surface of a natural tooth, but in some instances could be a portion or a surface of an artificial tooth, e.g., a dental implant, or a non-natural surface or repair of a native tooth, e.g., a filling, crown, inlay, restoration, or the like. Thus, the phrase dental feature will generally refer to all natural and non-natural teeth in a patient's dentition. In a second aspect of the present invention, the attachment device is bonded to and/or formed over a dental feature in a desired location. The

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attachment device may be bonded to any of these features with any suitable bonding material, typically dental restorative composites. The location in which one or more of these attachment devices are bonded is dependent upon the desired repositioning goal. The devices may be bonded to any surface of the dental features and may be placed singly or in groups. Likewise, a given attachment device may be bonded to surfaces of more than one dental feature. In a preferred embodiment, an attachment device may be placed on each of two teeth located on opposite sides of one or a contiguous group of teeth. When an elastic positioning appliance is inserted and attached to the two attachment devices, an intrusive force may be applied to the tooth or teeth in between. This is counterintuitive to the methods of conventional orthodontics in which brackets are bonded to the teeth that require repositioning.

In a third aspect of the present invention, the attachment devices may be constructed from variety of materials, including but not limited to metals, glass or silicone filled polymers, and other composite materials. Such materials are typically designed to be chip, break and shear resistant for durability. The base of the attachment device may be constructed from the same or from different materials as the attachment body. Likewise, the attachment body may be permanently or removably mounted on the base or the body and base may be constructed as one entity.

In a preferred embodiment, the attachment device may be constructed from a polymer material or combination of materials which have been formulated to be sensitive to an environmental condition or external stimulus. Upon exposure to such a condition or stimulus, the material may undergo a predetermined state change, which may be temporary or permanent. For example, upon exposure, a rigid material may become temporarily malleable, allowing changes in geometry to be made. Upon removal of the condition or stimulus, the material may return to its original rigid state and geometry or it may return to its original rigid state with the new geometry. In the former case, such stimulus may be used to facilitate coupling an attachment device to an elastic positioning appliance. The stimulus may alter the geometry of the attachment device during insertion and placement of the appliance. Removal of the stimulus may allow the device to return to its original geometry for application of repositioning forces. A full description is provided in application Ser. No. 09/250,262, the full disclosure of which is incorporated herein by reference. In the latter case, such stimulus may be used to facilitate bonding of the attachment device to the surface of the dental feature. The stimulus may alter the state and geometry of the attachment device, or simply the base, to conform it to the surface of the dental feature to which it is to be bonded. Upon removal of the stimulus, the attachment device may remain in the new geometry, providing a larger contacting surface area for bonding.

Similarly, a malleable material may be molded into a desired form and polymerized by exposure to an environmental condition or stimulus. Such polymerization may permanently hold the material in the desired form. This may be useful in both constructing the attachment device and bonding the device to a dental surface. For example, malleable material may be inserted in a mold of an attachment device. Polymerization, as described above, may result in a rigid attachment device in the molded form. In a preferred embodiment, the mold of the attachment device may be an impression in the wall of an elastic positioning appliance. This may ensure proper surface geometry for association between the attachment device and the appliance. Likewise,

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polymerization of the material while the appliance is in place over the dental features may simultaneously bond the attachment device to the dental feature. This may ensure proper alignment of the attachment device and the receiving impression in the appliance, and it may also preclude the need for additional bonding materials.

In a fourth aspect of the present invention, methods are provided to produce and/or bond an attachment device to a dental feature. Three preferred embodiments are applicable for use with elastic repositioning appliances or similarly fabricated devices and are as follows: 1) basic casting, 2) casting with polymerizing material and 3) computer-aided casting with polymerizing material. An example of basic casting involves producing two identical attachment devices by any means and comprised of any material(s). One attachment device may be placed in a desired location on a dental surface of the patient. The other attachment device may be placed in the identical location on a mold replicating at least the dental surface. An elastic positioning appliance or similar device may be formed over the mold containing the attachment device. Upon removal, a negative impression of the attachment device may be seen in the wall of the elastic positioning appliance. Therefore, when the appliance is inserted and seated in position by the patient, the impression in the appliance will correspond with the attachment device bonded to the dental surface. If the attachment device is to be used as a point of purchase to effect movement of the dental feature to which it is attached, the attachment device may be bonded to the dental feature in a position or orientation that differs from the mold. Therefore, when the appliance is inserted by the patient, the impression in the appliance will be slightly out of alignment with the attachment device. This will apply force to the attachment device, resulting in gradual repositioning of the device and underlying dental feature.

The method of casting with polymerizing material is similar to basic casting. Like basic casting, an attachment device of any design and material is placed in a desired location on a mold replicating at least the dental surface of interest. Again, an elastic positioning appliance or similarly fabricated device may be formed over the mold containing the attachment device, creating a negative impression of the attachment device in the wall of the appliance. At this point, a malleable polymerizing material may be placed into the negative impression in the appliance. When the appliance is inserted and seated in position in the oral cavity, the polymerizing material will be in contact with the dental surface and will be in the proper position. The material may be polymerized by any means, typically by an external stimulus or environmental condition. Polymerization may simultaneously harden the material and bond the material to the dental surface. Upon removal of the appliance, the formed attachment device may remain in place on the dental surface.

The method of computer-aided casting with polymerizing material is similar to the methods described above, yet differs in the steps of creating the appliance. Here, a 3-D computerized image of the attachment device is virtually placed in a desired location on an image of the dental surface. A mold is produced from the images using any computer-guided model fabrication system, such as stereolithography, CNC machining, and laser machining. The result is a mold of at least the dental surface of interest with a replica of the attachment device in proper position. At this point, an elastic positioning appliance or similarly fabricated device may be formed over the mold containing the attachment device, creating a negative impression of the attachment device in the wall of the appliance. Again, a

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malleable polymerizing material may be placed into the negative impression in the appliance. When the appliance is inserted and seated in position in the oral cavity, the material may be polymerized, leaving a formed attachment device in place on the dental surface when the appliance is removed.

In a fifth aspect of the present invention, an additional method is provided to produce and/or bond an attachment device to a dental feature. Two preferred embodiments are applicable for use with any dental appliances. The first embodiment involves a multi-tooth template which may be used to produce and/or bond an attachment device to a dental feature. The multi-tooth template may be thin and flexible to fit over multiple dental features at once, allowing multiple attachment devices to be placed at the same time. Receptacles may be present in the template to receive a polymerizing material. When the template is inserted and seated in position in the oral cavity, the polymerizing material will be in contact with the dental surface and will be in the proper position. The material may be polymerized by any means, typically by an external stimulus or environmental condition. Polymerization may simultaneously harden the material and bond the material to the dental surface. Upon removal of the template, the formed attachment device may remain in place on the dental surface. This method may be similar or identical to casting with polymerizing material and computer-aided casting with polymerizing material, however it may differ in that the template may not be used as the repositioning appliance. This difference may afford the use of template designs that are not applicable to repositioning appliances. For example, the template may be comprised of a material that is unsuitable for a repositioning appliance, or it may contain additional design features, such as handles, that would interfere with such usage. Similarly, the template may be fabricated from a mold of the patient's present tooth configuration, rather than the tooth configuration prescribed by an elastic positioning appliance. This may facilitate the method of attachment device production and/or bonding due to the closer fit of the template to the tooth configuration.

The second embodiment involves a single-tooth template which may be used to produce and/or bond an attachment device to a dental feature. The single-tooth template may be more rigid and may fit over a single dental feature. The template may be comprised of one or more receptacles to receive polymerizing material. When applied to the target surface of the dental feature, the material may be polymerized by any means previously described. The resulting attachment device is properly shaped and bonded in place. Alternatively, the single-tooth template may be comprised of a receptacle that is rigid, to receive the polymerizing material, surrounded by a thin, film-like portion of material that conforms to the dental feature. The thin, flexible area may contain an adhesive with which to hold the template in place on the dental feature. The material may then be polymerized to form the attachment device. When the procedure is complete, the template may be peeled off and discarded.

Single-tooth and multi-tooth templates may allow the production and placement of one or more attachment devices to a dental feature independent of the geometry of certain adjacent dental features. Thus, a template may be used throughout various stages of orthodontic repositioning treatment. This may be useful to replace an attachment device which has broken off mid-treatment or to place new attachment devices throughout treatment. As described above, at least one receptacle may be present in the template to receive a polymerizing material. When the template is

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inserted and seated in position in the oral cavity, the polymerizing material will be in contact with the dental surface and will be in the proper position. The material may be polymerized by any means, typically by an external stimulus or environmental condition. Polymerization may simultaneously harden the material and bond the material to the dental surface. Upon removal of the template, the formed attachment device may remain in place on the dental surface. Alternatively, templates may be used to bond any attachment device to a dental feature surface. For example, a pre-fabricated attachment device may be bonded to a surface with the use of a template. An attachment device may be inserted in a receptacle of a template, adhesive applied to the base of the attachment device and the template applied to the dental surface. After bonding has occurred, the template may be removed. Thus, the template may provide proper positioning and orientation. Likewise, a template may be used to form an attachment device using a polymerizing material, and then used again to bond the attachment device to a dental surface.

In a sixth aspect of the present invention, a method is provided to improve the production of templates or elastic positioning appliances. In a preferred embodiment, additional structures are provided in the mold of the dental feature with desired attachment device. The structures may be of any geometry and are typically placed near the gingival surface. When a template or appliance is thermoformed over the mold and additional structures, the structures provide a protrusion which aids in drawing the template or appliance from the mold. The protrusion may then be removed before use.

In a further aspect of the present invention, a method is provided to further improve the production of templates or elastic positioning appliances. In some cases, it may be desired to alter a template or appliance after it has been removed from a mold. Such alterations may include trimming edges or removing portions to prevent interference with specific devices or dental features. For example, it may be desirable to produce an elastic appliance with a window in a particular location corresponding to the placement of an attachment device. To ensure proper location of the window, a structure may be provided in the mold at the same location to aid in the creation of the window. In a preferred embodiment, a structure of spherical geometry may be provided in the mold at the desired location. Thermoforming of the appliance may result in a spherical protrusion at the location of the structure. After removal of the appliance from the mold, the spherical protrusion may be removed by cutting, filing, sawing, or any other means of removal. Thus, a window with a shape corresponding to the cross section of the structure, in this case a circle, may remain. As a result, a template or positioning appliance may be produced to cover desired dental features or to provide windows to expose such features.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a patient's tooth having an attachment device of the present invention bonded thereto.

FIGS. 2A and 2B illustrate exemplary attachment devices having broad bonding bases attached thereto.

FIGS. 3A and 3B illustrate attachment devices similar to those illustrated in FIGS. 2A and 2B, except that the attachment base is integral with the attachment body.

FIGS. 4 and 4A are top and side view, respectively, of an exemplary attachment device having a hemispherical attachment body in the form of a simple "bump." FIG. 4B is a

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perspective view of a similar attachment device with an elongated attachment body.

FIG. 5 illustrates an attachment device having an elastic band connected to a hook portion thereof.

FIG. 6 illustrates an attachment device similar to that shown in FIG. 4 which is attached to a positioning appliance via an adhesive layer.

FIG. 7 illustrates an exemplary wedge-shaped attachment device of the present invention in combination with a dental positioning appliance having cavities formed therein for removably receiving the attachment devices.

FIG. 8 is a detailed view of the attachment device of FIG. 7.

FIGS. 9A-9L are perspective views of a series of exemplary attachment devices with sloping angles constructed in accordance with the principles of the present invention.

FIGS. 10A-10F are front views of a series of attachment devices having wedge-shaped structures with different front end geometries.

FIG. 11 illustrates a method according to the present invention for intruding a tooth located between a pair of teeth having attachment devices thereon.

FIGS. 12A and 12B illustrate the mounting of an attachment device according to the present invention to a tooth surface.

FIGS. 13A-13D illustrate an embodiment of the method of basic casting.

FIGS. 14A-14C illustrates features of the method of casting with a polymerizing material.

FIG. 14D includes a series of cross-sectional views further describing the method of FIGS. 14A-14C.

FIGS. 15A-15C illustrates features of the method if computer-aided casting with polymerizing material.

FIG. 16 illustrates an embodiment of a multi-tooth template having a handle for use in in situ formation of attachment devices according to the methods of the present invention.

FIGS. 17A and 17B illustrate embodiments of single-tooth templates having handles for use in the methods of the present invention.

FIG. 18 illustrates a method according to the present invention for forming a window in a tooth positioning appliance using a feature formed in a mold according to the methods of the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment. Preferred embodiments involve elastic repositioning appliances or similarly fabricated devices, however the present invention is applicable to any type of removable appliance. Systems for removably attaching an appliance typically involve the use of one or more attachment devices positioned on at least one dental feature.

Referring to FIG. 1, a preferred embodiment of an attachment device 100 is shown bonded to a tooth 103 above the gingiva 104. The attachment device 100 may be comprised of an attachment body 101 having a base 102, which may be integral or separate and permanently or removably joined. Additional embodiments of attachment bodies 101 are depicted in FIG. 2 and FIG. 3. As seen in FIG. 2, the attachment device 100 may have a base 102 which is broader

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than the attachment body 102 to increase bonding surface area. Alternatively, the base 102 may simply be an end of the attachment body 101 for direct bonding to the tooth 103. Corresponding embodiments with such bases 102 are depicted in FIG. 3. The devices 100 may be bonded to any surface of a dental feature and may be located in one or more locations.

Specific shapes and designs may be particularly useful in certain locations. For example, attachment devices 100 positioned on the lingual surfaces of the teeth would characteristically prevent irritation to contacting tissues, such as the tongue. FIG. 4 depicts preferred embodiments of round-shaped attachment bodies 101 for such a purpose. A side view of such an attachment device 100 is shown in FIG. 4A. Bases 102 may be of any shape, thickness and orientation in relation to an attachment body 101. Likewise, a base 102 may have more than one discrete attachment body 101.

Additional devices may be used in conjunction with an attachment body 101 to attach an appliance to an attachment device 100. For example, adhesives, flexible bands or connecting ligatures may be used in conjunction with the design of the attachment body 101 to aid in connection to the appliance. FIG. 5 depicts an attachment body 101 with a flexible band 200 to attach the body 101 to an appliance (not shown). The body 101 is shaped so as to receive the band 200 and hold it in place, for example in a hook shape. FIG. 6 is side view illustrating an attachment body 101 with an adhesive 201 to aid in attachment to an appliance 105. Such an adhesive 201 may be any type of biocompatible material which may be applied by the patient, provided by the attachment device 100 or provided by the appliance 105. Likewise, the adhesive 201 may provide adhesive qualities over variable lengths of time.

Referring now to FIG. 7, a preferred embodiment of an attachment body 101 design is illustrated for use in aiding the proper seating of a removable elastic repositioning appliance 105 and anchoring the appliance 105 in place to apply repositioning forces. Such attachment bodies 101 may be located on any surface of a dental feature and may be placed singly or in groups. The design of the attachment body 101 may include a structure 300 which protrudes perpendicularly from the surface of the tooth 103. As shown in FIG. 8, the structure 300 may contain a sloping angle 301, from the surface of the tooth 103 to the opposing end of the structure 300, which is preferably less than 90 degrees. FIG. 9A presents a perspective view of a variety of attachment devices 100 having sloping angles 301 as described. FIG. 9B presents a perspective view of attachment devices 100 having a series of protruding structures 300 with sloping angles 301. These designs may provide a means for a type of ratcheting action that would allow an appliance to be seated or positioned at differing levels. It may be appreciated that such designs may serve the same function without sloping angles 301 and with differing geometries. Similarly, FIG. 10 presents a front view of a variety of attachment devices 100 having sloping angles 301.

Referring back to FIG. 7, when the elastic positioning appliance 105 is inserted for placement, the protruding structure 300 may grossly align with a matching negative impression 302 of the structure 300 formed into the appliance 105. As the appliance 105 is seated, the slope of the protruding structure 300 may guide the appliance 105 into the proper position. Once in position, the attachment device 100 may serve as an anchor for the appliance 105 to apply repositioning forces. Additionally, the elastic appliance 105 and/or the attachment device 100 may change in shape, stiffness or orientation to implement such anchoring. These

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changes may be the result of state changes of one or more layers of the material when subjected to a certain environmental condition, such as non-physiologic pH, temperature, ionic strength or external stimulus.

Repositioning forces as a result of anchoring may take many forms. In a preferred embodiment illustrated in FIG. 11, attachment devices 100 may be placed to serve as anchors to apply directed intrusive repositioning forces. As shown in Step 1, two attachment devices 100 may be placed on each of two teeth 103 located on opposite sides of one or a contiguous group of between teeth 103'. In Step 2, an elastic repositioning appliance 105 is produced with an inset profile 303 at the location in which intrusive force is to be applied. In Step 3, the appliance 105 is inserted for placement over the teeth 103,103'. In Step 4, the appliance 105 is attached to the attachment devices 100 which serve to anchor the appliance 105. As a result, intrusive forces, depicted by a downward arrow 304, are applied to the between teeth 103'. Over time, the intrusive forces will affect intrusion of the between teeth 103', as shown in Step 5. It may be appreciated that the profile of the appliance 105 may take a variety of forms to create intrusive forces, depending on the overall configuration of the teeth 103 and the between teeth 103'. For example, in the case where the between teeth 103' are initially more extruded than the adjacent teeth 103, the appliance 105 may have a profile that is generally flat, with no inset profile 303. Thus, when the appliance 105 is attached to the attachment devices 100, intrusive forces will again be applied to the between teeth 103'. The use of bonded devices, such as attachment devices 100, to apply repositioning forces to a tooth without bonded devices is distinct in that it is counterintuitive to the methods of conventional orthodontics in which brackets are bonded to the teeth that require repositioning.

As previously described, the attachment devices 100 may be constructed from a variety of materials, including materials which have been formulated to be sensitive to an environmental condition or external stimulus. For example, upon exposure, a rigid material may become temporarily malleable, allowing changes in geometry to be made. Upon removal of the condition or stimulus, the material may return to its original rigid state with the new geometry. This may be particularly useful in conforming the geometry of an attachment device 100 to better interface an uneven or curved surface. As shown in FIG. 12A, an attachment device 100 may be originally constructed to have an attachment base 102 which does not conform to the dental surface 305 to which it is to be bonded. In this case, the material may be exposed to a stimulus to which it is sensitive, initiating a state change in the material. Such a stimulus may be a change in the oral environment to a non-physiologic pH, temperature, ionic strength or liquid absorption. Likewise, the stimulus may be of an external source such as light, magnetism, electricity, radiowaves, or chemicals. Such a state change may allow the material to become flexible so the attachment base 102 may conform to the dental surface 305, as shown in FIG. 12B.

Similarly, a permanent state change in the material may occur as a result of applying a stimulus. Thus, the material may be malleable in its initial state, allowing it to be molded into a desired shape. The material may then be polymerized due to application of a stimulus. Likewise, polymerization may occur over time from the point of initial formulation, as in the case of an air or moisture cure. Polymerization may simultaneously harden the material and form a bond between the material and any interfacing surface.

A series of methods are provided based on these polymerization characteristics to produce and/or bond an attach-

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ment device 100 to a dental feature, such as a tooth 103. Three preferred embodiments are applicable for use with elastic positioning appliances and are as follows: 1) basic casting, 2) casting with polymerizing material and 3) computer-aided casting with polymerizing material.

FIGS. 13A-D characterize an embodiment of the method of basic casting. Basic casting involves first producing two identical attachment devices 100 by any means. As shown in FIG. 13A, one attachment device 100 may be placed in a desired location on a mold 306 which replicates the dental feature of interest, in this case a tooth 103. As shown in FIG. 13B, an elastic positioning appliance 105 may be formed over a mold 306 containing the attachment device 100. This is typically accomplished by heating a thermoformable polymer material and applying vacuum or pressure to form the polymer to the mold. Alternatively, reaction casting may be used to produce such an appliance. Upon removal, FIG. 13C, a negative impression 302 of the attachment device may be seen in the wall of the appliance 105. The other attachment device 100 is placed in the identical location and orientation on the dental feature of the patient corresponding to the mold 306. When the appliance 105 is inserted and seated in position, the impression 302 in the appliance 105 will correspond with the attachment device 100 bonded to the tooth 103, as illustrated in FIG. 13D.

The method of casting with a polymerizing material is similar to the method of basic casting. In one embodiment, an elastic positioning appliance 105 is formed over a mold 306 containing an attachment device 100, as previously depicted in FIGS. 13A-C. At this point, a malleable polymerizing material 400 may be placed into the negative impression 302 in the appliance 105. FIG. 14A is an enlarged view of the underside of a portion of the appliance 105, revealing a receiving cavity 401 for a tooth 103 and the negative impression 302 of an attachment device 100 filled with a polymerizing material 400. When the appliance 105 is seated in position in the oral cavity, FIG. 14B, the polymerizing material 400 will be in contact with the desired dental surface, in this case a tooth 103, and will be positioned in the proper location. The material 400 may be polymerized (depicted by jagged arrow 402) by any means, such as an external stimulus. Upon removal of the appliance 105, the formed attachment device 100 may remain in place on the tooth 103, as shown in FIG. 14C. Cross-sectional views of this method or presented in FIG. 14D.

The method of computer-aided casting with polymerizing material 400 is similar to the methods described above, yet differs in the steps of creating the appliance 105. In one embodiment, a computerized image of the attachment device 100 is virtually placed in a desired location on an image of the dental surface. From these images, a mold 306 is produced comprising the dental surface of interest, in this case a tooth 103, with an attachment device replica 403 in proper position. At this point, an elastic positioning appliance 105 may be formed over the mold 306, as seen in FIG. 15A. Upon removal, FIG. 15B, a negative impression 302 of the attachment device 100 may be seen in the wall of the appliance 105. At this point, the attachment device 100 may be formed and bonded to the dental feature by methods previously depicted in FIGS. 14A-C.

Two additional methods are provided to produce and/or bond an attachment device 100 to a dental feature, such as a tooth 103. These embodiments are applicable for use with any dental appliance. The first embodiment involves a multi-tooth template. The multi-tooth template may be similar or identical to an elastic repositioning appliance, and it may be used for casting with polymerizing material and

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computer-aided casting with polymerizing material, as described above. However, it may differ in that the template may not be used as the repositioning appliance. Therefore, multi-tooth template designs may include features that are not applicable to such use. For example, in FIG. 16, one embodiment depicts a type of handle 403 with which to easily place and remove the multi-tooth template 404. As shown, the template 404 may contain receiving cavities 401 for only a select portion of teeth and it may include negative impressions 302 for attachment devices 100 on more than one tooth 103.

The second embodiment involves a single-tooth template. The single-tooth template is similar to the multi-tooth template 404, however it may be more rigid as it is designed to fit over a single dental feature. As shown in FIG. 17A, one embodiment may contain a portion of a receiving cavity 401 which conforms to a portion of the surface of the target tooth 103. It may also contain a type of handle 403 to aid in placement of the single-tooth template 405. Production and bonding of an attachment device 100 to the tooth 103 may be accomplished by casting with polymerizing material or computer-aided casting with polymerizing material. Similarly, an additional embodiment of a single-tooth template 405 may be seen in FIG. 17B. Here the template 405 may be thin and flexible to conform to a portion of a dental feature. It may contain adhesive ring 406 around the negative impression 302 of the attachment device 100. The adhesive ring 406 will hold the template 405 in place on the dental feature, in this case a tooth 103, throughout the casting with polymerizing material or computer-aided casting with polymerizing material to produce and bond the attachment device 100. A pull-tab 407 may be present to facilitate a peeling removal of the template 405.

A method to further aid in production of templates or elastic positioning appliances is depicted in FIG. 18. Here, an embodiment of an improved method for producing a window of particular shape and location in an elastic appliance is presented to prevent interference with specific devices or dental features. As shown in Step 1, a mold 306 is created with an added structure 500 in the location where the window is desired. The shape of the structure 500 should provide a cross-section (dashed line 501) that will form the shape of the window. In this example, the structure 500 is a sphere having a circular cross-section 501. In Step 2, a polymer sheet is thermoformed over the mold 306, and an elastic appliance 105 is produced with a spherical protrusion 502 in the location of the structure 500. After removal of the appliance 105 from the mold 306, the spherical protrusion 502 may be removed, as shown in Step 3, leaving a window 503 with the same shape as the cross-section 501 of the structure 500. In Step 4, the appliance 105 may be positioned on the dental features of the patient, allowing an attachment device 100 to be accessible through a window 503.

What is claimed is:

1. A method for producing digital models of dental positioning appliances, said method comprising:

providing a digital model of a patient's dentition;

producing a plurality of modified digital models of the dentition, wherein the modified models represent successive stages of an orthodontic treatment;

providing a digital model of at least one attachment device; and

positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

2. A method as in claim 1, wherein providing a digital model of the patient's dentition comprises scanning the patient's teeth.

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3. A method as in claim 1, wherein providing a digital model of the patient's dentition comprises scanning a mold of the patient's teeth.

4. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:

presenting a visual image based on the digital model of the patient's dentition;

manipulating the visual image to reposition individual teeth in the visual image;

producing a digital data set representing the final tooth arrangement with repositioned teeth as observed in the image; and

producing the plurality of modified digital models as a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.

5. A method as in claim 4, wherein the manipulating step comprises:

defining boundaries about at least some of the individual teeth; and

moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set.

6. A method as in claim 1, wherein producing a plurality of modified digital models of the dentition comprises:

providing a computer system having at least one processor and memory;

providing to the computer system the digital model of the patient's dentition;

providing to the computer system a digital model set representing a final tooth arrangement;

producing using the computer system the plurality of models based on both of the previously provided initial and final digital data sets.

7. A method as in claim 6, wherein the step of providing a digital model set representing a final tooth arrangement comprises:

defining boundaries about at least some of the individual teeth on a visual image provided by the computer system; and

moving at least some of the tooth boundaries relative to the other teeth in the visual image to produce the final data set.

8. A method as in claim 6, wherein the step of producing the plurality of models comprises determining positional differences between the initial digital model and the final digital model and interpolating said differences.

9. A method as in claim 8, wherein the interpolating step comprises linear interpolation.

10. A method as in claim 8, wherein the interpolating step comprises nonlinear interpolation.

11. A method as in claim 8, further comprising defining one or more key frames between the initial digital tooth model and final digital tooth model and interpolating between the key frames.

12. A method as in claim 1, wherein providing a digital model of at least one attachment device comprises selecting the digital model of the attachment from a library of such attachments.

13. A set of dental positioning appliances, said set comprising a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment, wherein at least some of said appliances has a receptacle positioned to receive an attachment device on a patient's teeth when each of said appliances is successfully worn over the teeth during the orthodontic treatment.

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14. A set of dental positioning appliances as in claim 13, including at least a first appliance, an intermediate appliance, and a final appliance.

15. A set of dental positioning appliances as in claim 14, including at least two intermediate appliances. 5

16. A set of dental positioning appliances as in claim 15, including at least ten intermediate appliances.

17. A set of dental positioning appliances as in claim 16, including at least twenty-five intermediate appliances.

18. A set of dental positioning appliances as in claim 13, 10 wherein the tooth positions defined by the cavities in each appliance differ from those defined by an immediately prior appliance by no more than 2 mm.

19. An improved method for repositioning teeth using appliances comprising polymeric shells having cavities 15 shaped to receive and resiliently reposition teeth to a final tooth arrangement, wherein the improvement comprises:

placing an attachment device on at least one tooth of a patient; and

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providing a plurality of polymeric shell appliances to be worn successively by the patient to reposition the patient's teeth, wherein each of the appliance shells has a receptacle for receiving the attachment device when the shell appliance is worn over the teeth and wherein the position of the receptacle in the appliance is selected to transmit a force to move the tooth.

20. A method for fabricating a dental positioning appliance, said method comprising:

providing a digital model of a patient's teeth;
providing a digital model of at least one attachment device;
positioning the digital model of the attachment device on the digital model of the teeth to produce a combined digital model;
fabricating the dental positioning appliance based on the combined digital model.

* * * * *

A3013

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,705,863 B2
APPLICATION NO. : 10/040269
DATED : March 16, 2004
INVENTOR(S) : Phan et al.

Page 1 of 1

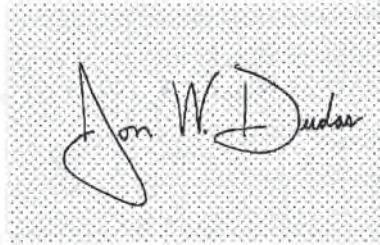
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title Page

Item (63), please delete "which is a continuation-in-part of application No. 09/466,353, filed on Dec. 17, 1999, now Pat No. 6,398,548, which is a continuation of application No. PCT/US98/12861," and insert -- which is a continuation-in-part of application No. PCT/US98/12861, --.

Signed and Sealed this

Second Day of January, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

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(12) EX PARTE REEXAMINATION CERTIFICATE (6092nd)
United States Patent
Phan et al.

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(54) ATTACHMENT DEVICES AND METHODS
FOR A DENTAL APPLIANCE

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(*) Notice: This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation-in-part of application No. 09/454,278, filed on Dec. 3, 1999, now Pat. No. 6,309,215, which is a continuation-in-part of application No. 09/250,962, filed on Feb. 16, 1999, now Pat. No. 6,183,248, which is a continuation-in-part of application No. 09/169,034, filed on Oct. 8, 1998, now Pat. No. 6,471,511, which is a continuation-in-part of application No. PCT/US98/12861, filed on Jun. 19, 1998, which is a continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.

(60) Provisional application No. 60/110,189, filed on Nov. 30, 1999, provisional application No. 60/110,881, filed on Dec. 4, 1998, and provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) **Int. Cl.**
A61C 13/00 (2006.01)

(52) **U.S. Cl.** 433/24; 433/6

(58) Field of Classification Search None
 See application file for complete search history.

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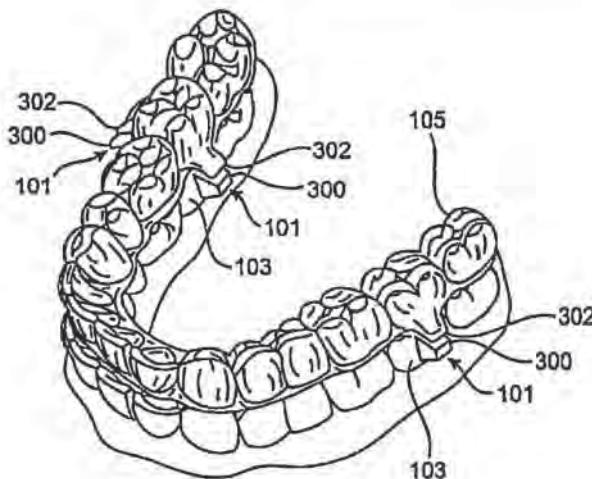
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(57) ABSTRACT

The present invention provides improved systems and methods for removably attaching a dental positioning appliance to the dental features of a patient during orthodontic treatment. These appliances function by applying force to specific surfaces of the teeth or dental features to cause directed movement. The application of force is improved by the use of one or more attachment devices which may be positioned on the teeth or dental features to provide the appropriate physical features. Specific design and location of these attachment devices may provide newly achievable and/or more effective repositioning forces, anchoring ability and appliance retention. The systems and methods of the present invention provide the design, production and use of such attachment devices with removable dental positioning appliances in orthodontic treatment.



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**EX PARTE
REEXAMINATION CERTIFICATE
ISSUED UNDER 35 U.S.C. 307**

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets [] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE
SPECIFICATION AFFECTED BY AMENDMENT
ARE PRINTED HEREIN.

Column 10, lines 34-56:

Referring now to FIG. 7, a preferred embodiment of an attachment body 101 design is illustrated for use in aiding the proper seating of a removable elastic repositioning appliance 105 and anchoring the appliance 105 in place to apply repositioning forces. Such attachment bodies 101 may be located on any surface of a dental feature and may be placed singly or in groups. The design of the attachment body 101 may include a structure 300 which protrudes perpendicularly from the surface of the tooth 103. As shown in FIG. 8, the structure 300 may contain a sloping angle 301, from the surface of the tooth 103 to the opposing end of the structure 300, which is preferably less than 90 degrees. FIG. 9A presents a perspective view of a variety of attachment devices 100 having sloping angles 301 as described. [FIG. 9B presents a perspective view] FIGS. 9K and 9L present perspective views of attachment devices 100 having a series of protruding structures 300 with sloping angles 301. These designs may provide a means for a type of ratcheting action that would allow an appliance to be seated or positioned at differing levels. It may be appreciated that such designs may serve the same function without sloping angles 301 and with differing geometries. Similarly, FIG. 10 presents a front view of a variety of attachment devices 100 having sloping angles 301.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 19-20 is confirmed.

Claim 13 is cancelled.

Claims 1 and 14-18 are determined to be patentable as amended.

Claims 2-12, dependent on an amended claim, are determined to be patentable.

New claims 21-58 are determined to be patentable.

1. A method for producing digital models of dental positioning appliances, said method comprising:
providing a digital model of a patient's dentition;
producing a plurality of modified digital models of the dentition, wherein the modified models represent successive treatment stages of an orthodontic treatment and wherein each modified model or a product of such model is to be used in fabrication of a distinct successive incremental dental positioning appliance associated with the respective treatment stage of that modified model;

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providing a digital model of at least one attachment device; and
positioning the digital model of the attachment device on at least some of the plurality of modified digital models.

- 5 14. A set of dental positioning appliances as in claim [13] 22, including at least a first appliance, an intermediate appliance, and a final appliance.
- 10 15. A set of dental positioning appliances as in claim [14] 22, including at least two intermediate appliances.
- 15 16. A set of dental positioning appliances as in claim [15] 22, including at least ten intermediate appliances.
- 20 17. A set of dental positioning appliances as in claim [16] 22, including at least twenty-five intermediate appliances.
- 25 18. A set of dental positioning appliances as in claim [13] 22, wherein the tooth positions defined by the cavities in each appliance differ from those defined by an immediately prior appliance by no more than [2] 0.5 mm.

21. A set of dental positioning appliances, said set comprising a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment, wherein at least some of said appliances representing earlier stages of treatment have a first receptacle positioned to receive an attachment device on a patient's teeth when each of said appliances is successively worn over the teeth during the orthodontic treatment and wherein some of said appliances representing later stages of treatment have a new receptacle not found on the appliances representing earlier stages of treatment.

22. A set of dental positioning appliances as in claim 21, wherein said new receptacle is positioned to receive an attachment device on a patient's tooth when each of some of said appliances representing later stages of treatment is successively worn over the teeth during the orthodontic treatment.

30 23. A set of dental positioning appliances as in claim 22, wherein said new receptacle is positioned at a different position on the appliance than is the first receptacle.

24. A set of dental positioning appliances as in claim 22, wherein said new receptacle is positioned to receive an attachment device on a different one of the patient's teeth than is the first receptacle.

35 25. A set of dental positioning appliances as in claim 22, wherein said new receptacle is positioned at a different location on the patient's tooth than is the first receptacle.

40 26. A set of dental positioning appliances as in claim 22, wherein at least some of said appliances representing earlier stages of treatment each have at least two receptacles each positioned to receive a separate attachment device on a patient's teeth when each of said appliances is successively worn over the teeth during the orthodontic treatment and wherein at least some of said appliances representing later stages of treatment each have at least two new receptacles not found on the at least some of said appliances representing earlier stages of treatment.

45 27. A set of dental positioning appliances as in claim 21, wherein a first receptacle is positioned on the initial appliance of the orthodontic treatment.

28. A set of dental positioning appliances as in claim 27, wherein the new receptacle is not found on the initial appliance of the orthodontic treatment.

50 29. A set of dental positioning appliances as in claim 22, wherein at least one of the receptacles has a design such that it provides, in conjunction with the attachment device it receives, a ratcheting action.

65 30. A set of dental positioning appliances as in claim 22, wherein at least one of the receptacles provides, in conjunction with the attachment device it receives, a mating between

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receptacle and device that allows the appliance to be seated at different levels on a patient's teeth.

31. A set of dental positioning appliances, said set comprising a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment, wherein at least some of said appliances have a receptacle positioned to receive an attachment device on a patient's teeth when each of said appliances is successively worn over the teeth during the orthodontic treatment,

the set further including a removable template, having a geometry such that it can be placed over one or more of the teeth and also having a receptacle defining a shape for an attachment device and a position for such attachment device in relation to a tooth, and

the set also including an attachment device attached to a tooth and having a shape corresponding to the receptacle of the template, the device having been simultaneously formed in the template receptacle and attached to the tooth at the position defined by the receptacle of the template.

32. A set of dental positioning appliances as in claim 31, wherein the portion of attachment device in contact with the tooth conforms precisely to the shape of the portion of the tooth with which it is in contact.

33. A set of dental positioning appliances as in claim 31, wherein the attachment device is attached to the tooth without an additional bonding material beyond the material of the device.

34. A set of dental positioning appliances, said set comprising a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment, wherein at least some of said appliances have a receptacle positioned to receive an attachment device on a patient's teeth when each of said appliances is successively worn over the teeth during the orthodontic treatment; and

said set further comprising at least one attachment device configured such that it provides a ratcheting action when received in a receptacle on at least some of said appliances.

35. A set of dental positioning appliances as in claim 34, wherein the ratcheting action allows at least one of said appliances to be seated at differing levels on a patient's teeth.

36. A set of dental positioning appliances as in claim 34, wherein at least one attachment device has a series of protruding structures with sloping angles that facilitate a ratcheting action.

37. A set of dental positioning appliances, said set comprising

a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment, wherein at least some of said appliances represent earlier stages of treatment and some of said appliances represent later stages of treatment, and

at least some of said appliances representing earlier stages of treatment have a first receptacle positioned to receive a first attachment device on a patient's tooth when each of said appliances is successively worn over the teeth during the orthodontic treatment

said set further comprising a shell removable template wherein the template fits over one or more of the teeth after said earlier stages of treatment and wherein the template includes a receptacle for positioning a new attachment device on the teeth such new attachment not corresponding to a receptacle in said appliances representing earlier stages of treatment and

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wherein some of said appliances representing later stages of treatment have a new receptacle so positioned as to receive the new attachment device positioned by the receptacle in the template.

38. A set of dental positioning appliances as set out in claim 37, wherein the at least one different receptacle position is positioned to receive an attachment device on a different tooth than is the first receptacle.

39. A set of dental positioning appliances as set out in claim 21, wherein the new receptacle on some of said appliances representing later stages of treatment is capable of receiving a new attachment device placed on the patient's teeth after earlier stages of treatment.

40. An improved method for repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to a final tooth arrangement, wherein the improvement comprises:

placing an attachment device on at least one tooth of a patient by placing an attachment device material on the tooth and changing a state of the material to form and attach the attachment device to the tooth; and

providing a plurality of polymeric shell appliances to be worn successively by the patient to reposition the patient's teeth, wherein each of the appliance shells has a receptacle for receiving the attachment device when the shell appliance is worn over the teeth and wherein the position of the receptacle in the appliance is selected to transmit a force to move the tooth.

41. An improved method for repositioning teeth as in claim 40, wherein the step of placing an attachment device material on the tooth includes the use a template over the tooth.

42. An improved method for repositioning teeth as in claim 41, wherein the template includes a receptacle for receiving the attachment device material in a malleable state.

43. An improved method for repositioning teeth as in claim 42, wherein the malleable attachment device material is placed into the receptacle before the template is placed over the tooth.

44. An improved method for repositioning teeth as in claim 40, wherein the step of changing a state of the material includes changing an environmental condition.

45. An improved method for repositioning teeth as in claim 44, wherein the environmental condition changed is pH.

46. An improved method for repositioning teeth as in claim 40, wherein the step of changing a state of the material includes applying a stimulus to the material.

47. An improved method for repositioning teeth as in claim 46, wherein the stimulus applied to the material is light energy.

48. An improved method for repositioning teeth as in claim 40, further comprising the step of changing a state of the attachment device material prior to placing it on the tooth.

49. An improved method for repositioning teeth as in claim 40, wherein the attachment device material comprises a polymerizing material.

50. An improved method for repositioning teeth as in claim 49, wherein a stimulus is applied to the polymerizing material in the receptacle of the template to stimulate the change of state of the polymerizing material.

51. An improved method for repositioning teeth as in claim 50, wherein the stimulus applied comprises light energy.

52. An improved method for repositioning teeth as in claim 40, further comprising:

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putting at least one of the repositioning appliance shells over the teeth and using its receptacle to position an attachment device in the placing step.

53. An improved method for repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to a final tooth arrangement, wherein the improvement comprises:

placing a first attachment device on at least one tooth of a patient;

providing a first plurality of polymeric shell appliances to be worn successively by the patient to reposition the patient's teeth, wherein each of the appliance shells has a receptacle for receiving the attachment device when the shell appliance is worn over the teeth and wherein the position of the receptacle in the appliance is selected to transmit a force to move the tooth

putting at least one of the repositioning appliance shells of the first plurality over the teeth

after putting the at least one of the repositioning shells of the first plurality over the teeth, placing a new attachment device on at least one tooth of the patient; and providing additional polymeric shell appliances to be worn successively by the patient to reposition the patient's teeth, wherein at least some of the additional

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appliance shells have a receptacle for receiving the new attachment device when the shell appliance is worn over the teeth after the new attachment device has been placed.

54. A set of dental positioning appliances as set out in claim 21, comprising at least two first receptacles and at least two new receptacles.

55. A set of dental positioning appliances as set out in claim 37, wherein the at least one different receptacle position is positioned to receive an attachment device at a different position than that of the first receptacle.

56. A set of dental positioning appliances as set out in claim 37, comprising at least two first receptacles and at least two new receptacles.

57. A method as in claim 1, further comprising providing the produced plurality of modified digital models for use in fabricating a series of successive dental positioning appliances.

58. A method as in claim 1, wherein the successive stages represent successive stages of tooth movements and wherein the tooth movements of the successive stages are capable of being performed by a series of incremental dental positioning appliances.

* * * * *

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U.S. PATENT: 6,722,880
ISSUE DATE: April 20, 2004

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M. K. CARTER
Certifying Officer





US006722880B2

(12) **United States Patent**
Chishti et al.

(10) **Patent No.:** US 6,722,880 B2
(b) **Date of Patent:** *Apr. 20, 2004

(54) **METHOD AND SYSTEM FOR INCREMENTALLY MOVING TEETH**

(75) Inventors: Muhammad Chishti, Sunnyvale, CA (US); Kelsey Wirth, Palo Alto, CA (US)

(73) Assignee: Align Technology, Inc., Santa Clara, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 10/047,077

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(65) **Prior Publication Data**

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(63) Continuation of application No. 09/466,353, filed on Dec. 17, 1999, now Pat. No. 6,398,548, which is a continuation of application No. PCT/US98/12861, filed on Jun. 19, 1998, and a continuation-in-part of application No. 08/947,080, filed on Oct. 8, 1997, now Pat. No. 5,975,893.

(60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) Int. Cl. 7 A61C 3/00

(52) U.S. Cl. 433/24

(58) Field of Search 433/24, 213

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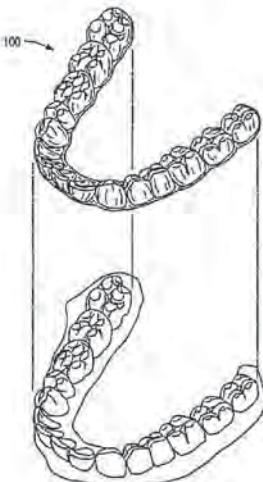
Primary Examiner—John J. Wilson

(74) Attorney, Agent, or Firm—Townsend and Townsend and Crew, LLP; Bao Tran, Esq.

(57) **ABSTRACT**

A system for repositioning teeth comprises a plurality of individual appliances. The appliances are configured to be placed successively on the patient's teeth and to incrementally reposition the teeth from an initial tooth arrangement, through a plurality of intermediate tooth arrangements, and to a final tooth arrangement. The system of appliances is usually configured at the outset of treatment so that the patient may progress through treatment without the need to have the treating professional perform each successive step in the procedure.

21 Claims, 19 Drawing Sheets



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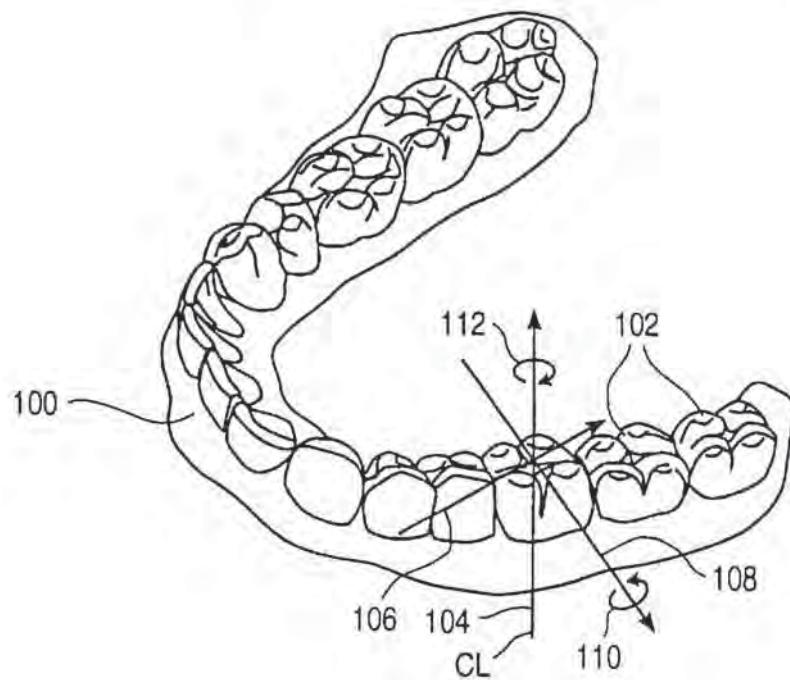


FIG. 1A

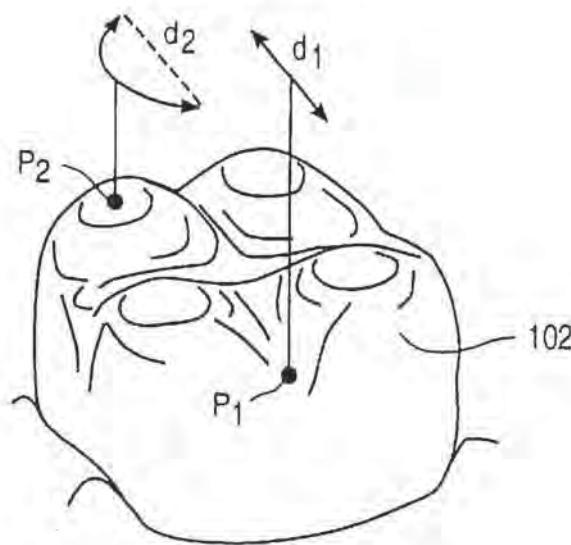


FIG. 1B

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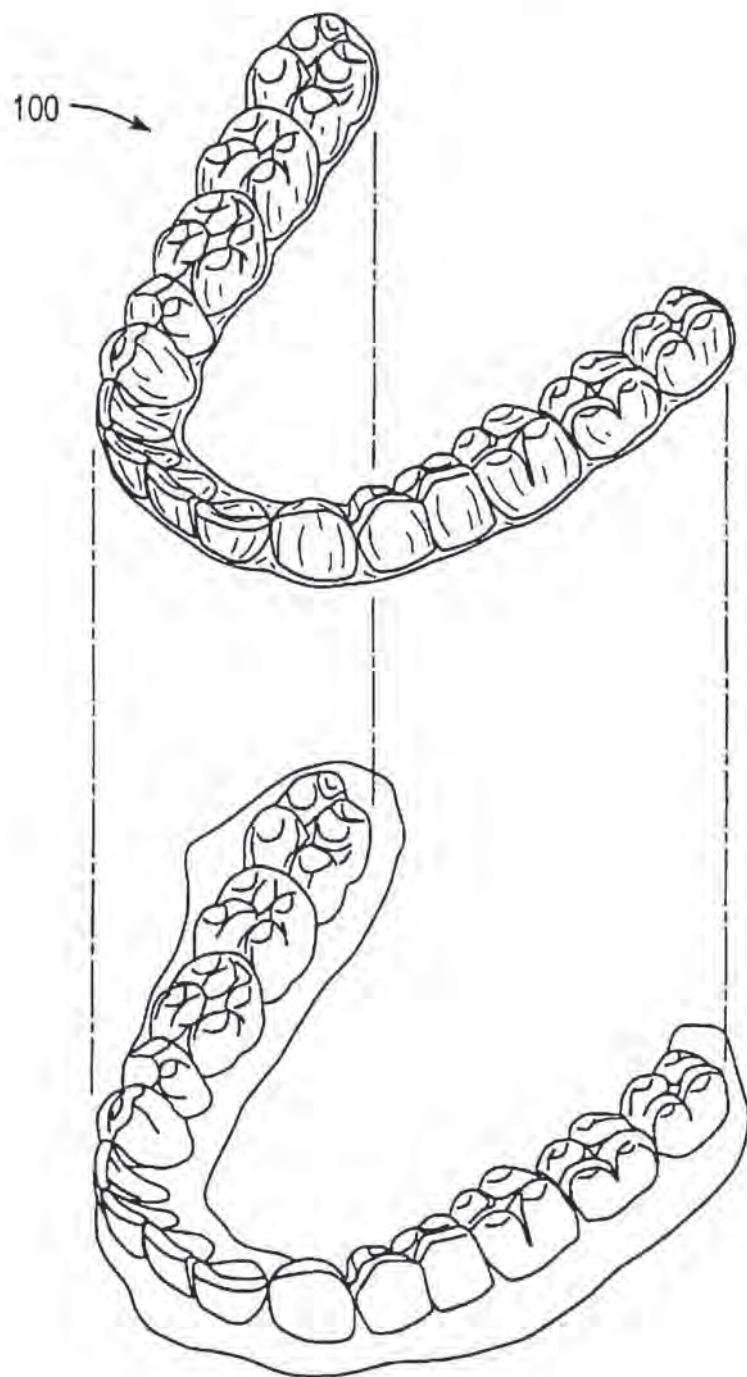


FIG. 1C

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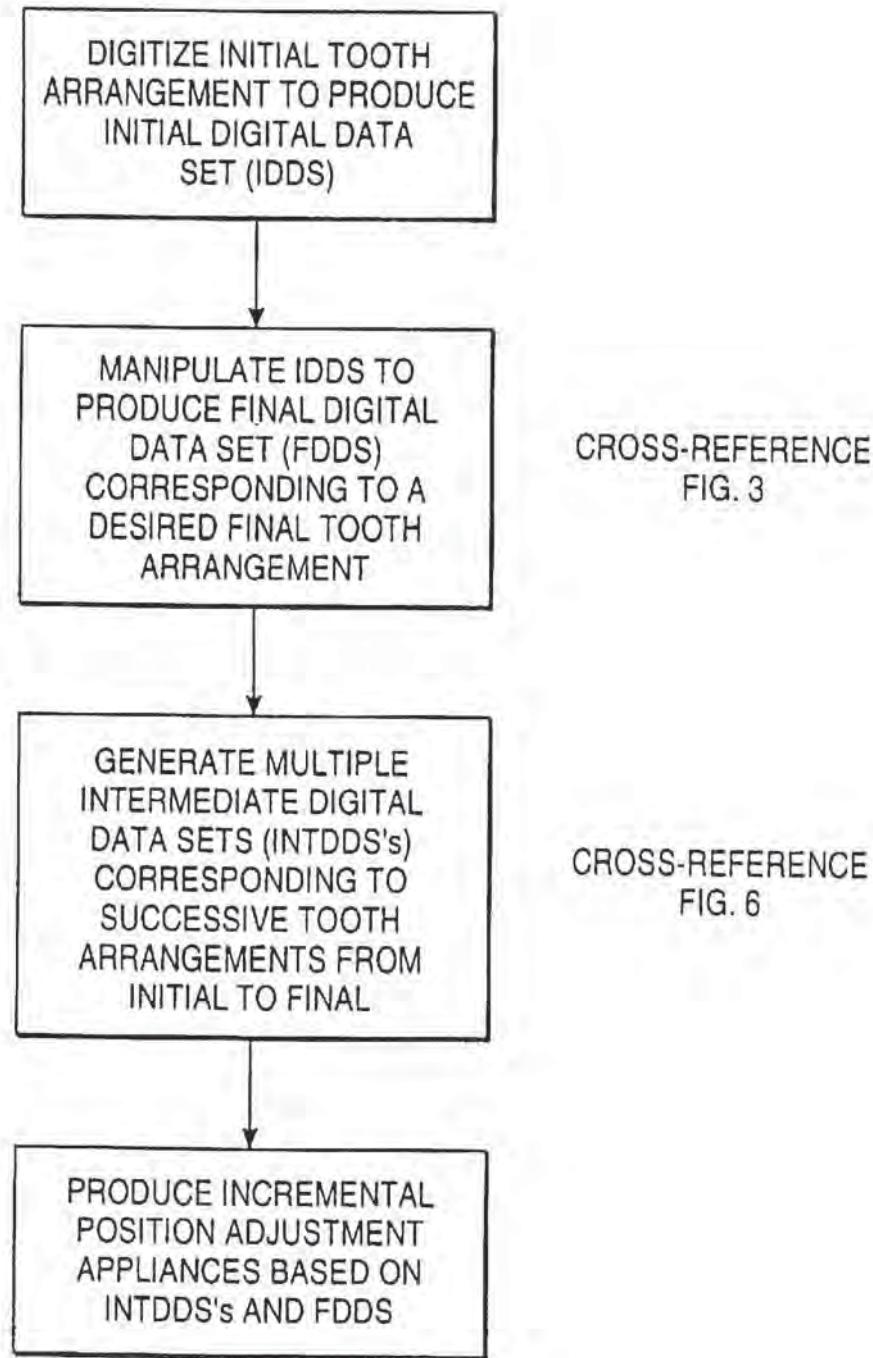


FIG. 2

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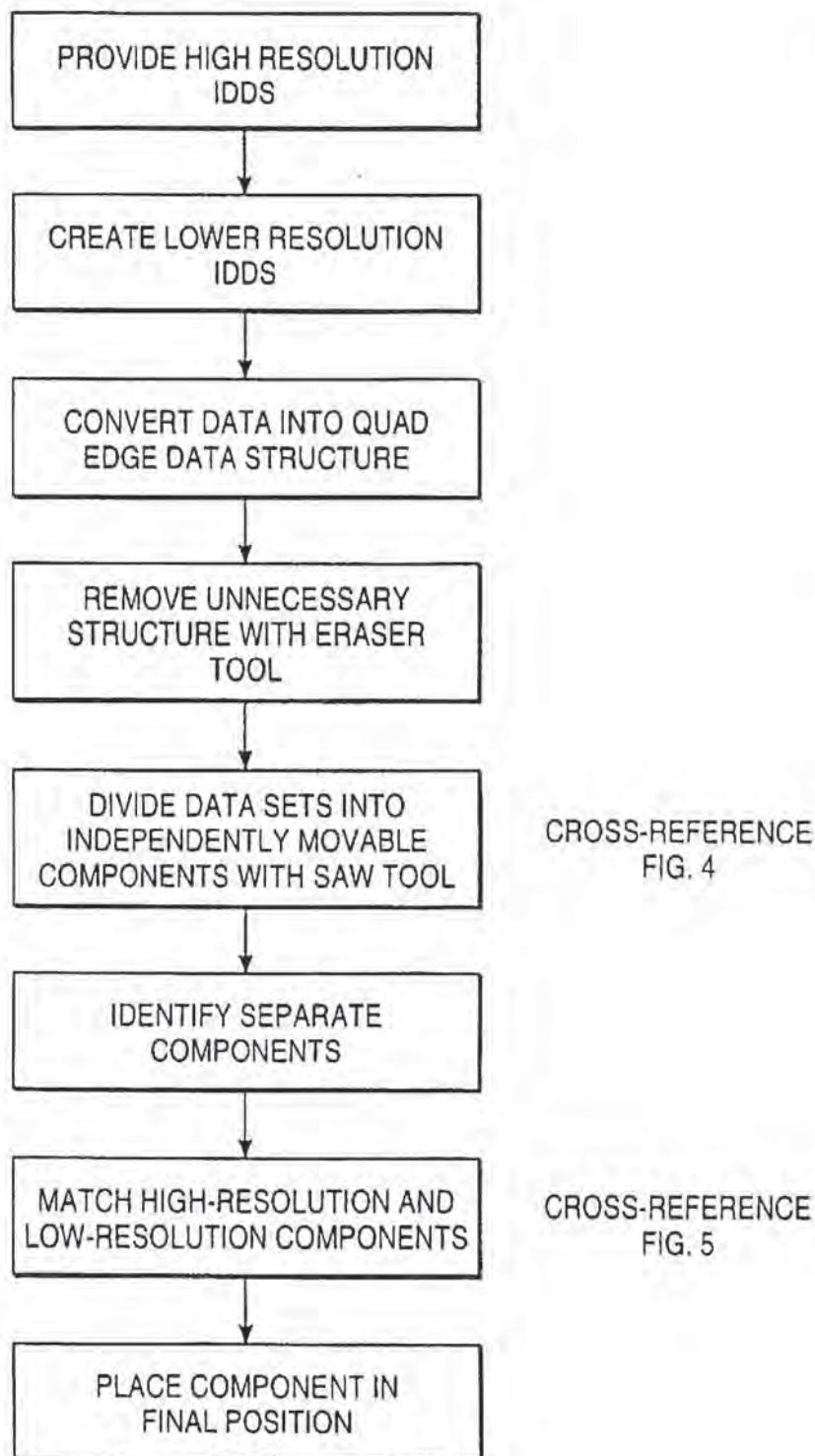


FIG. 3

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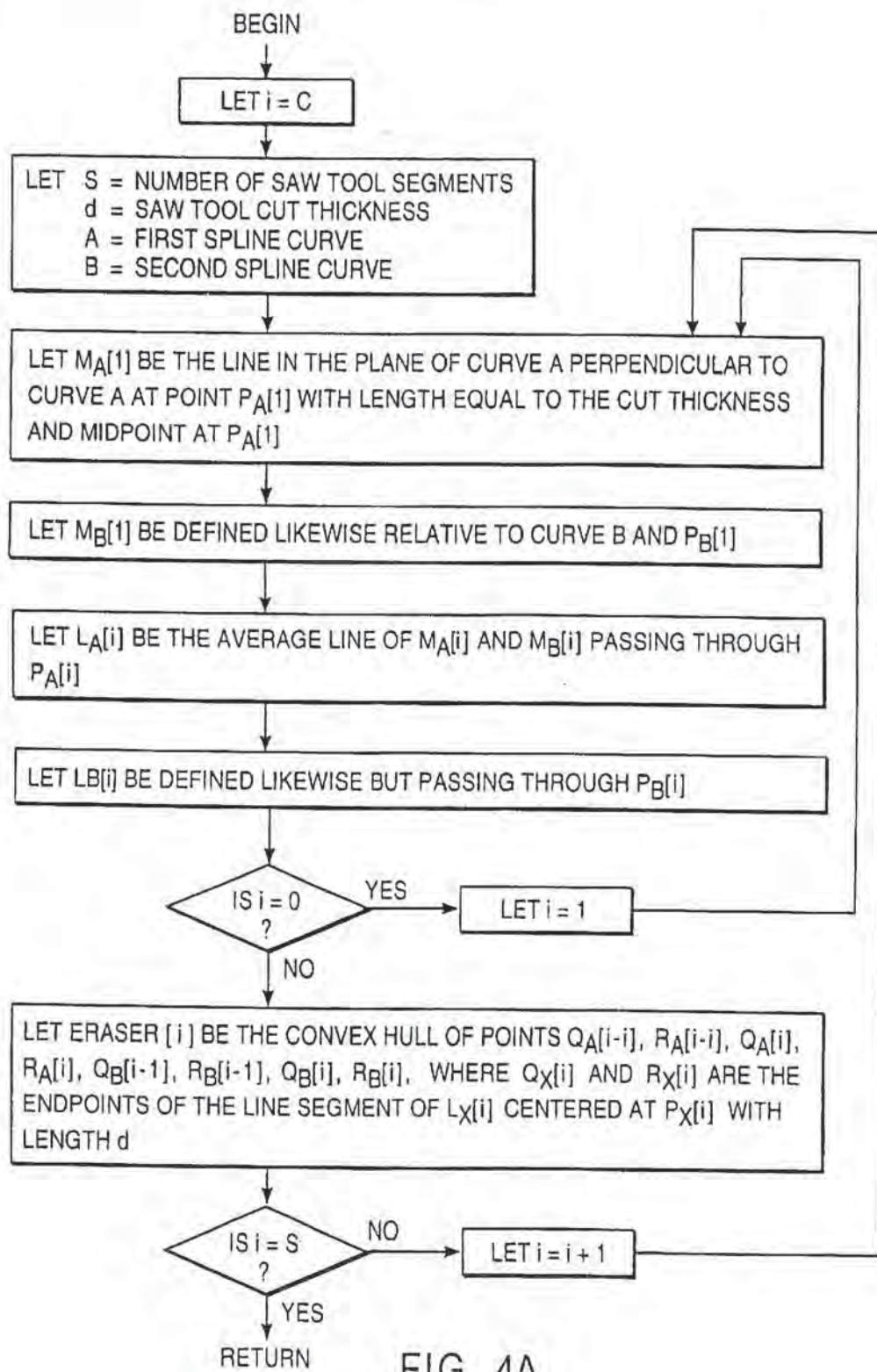


FIG. 4A

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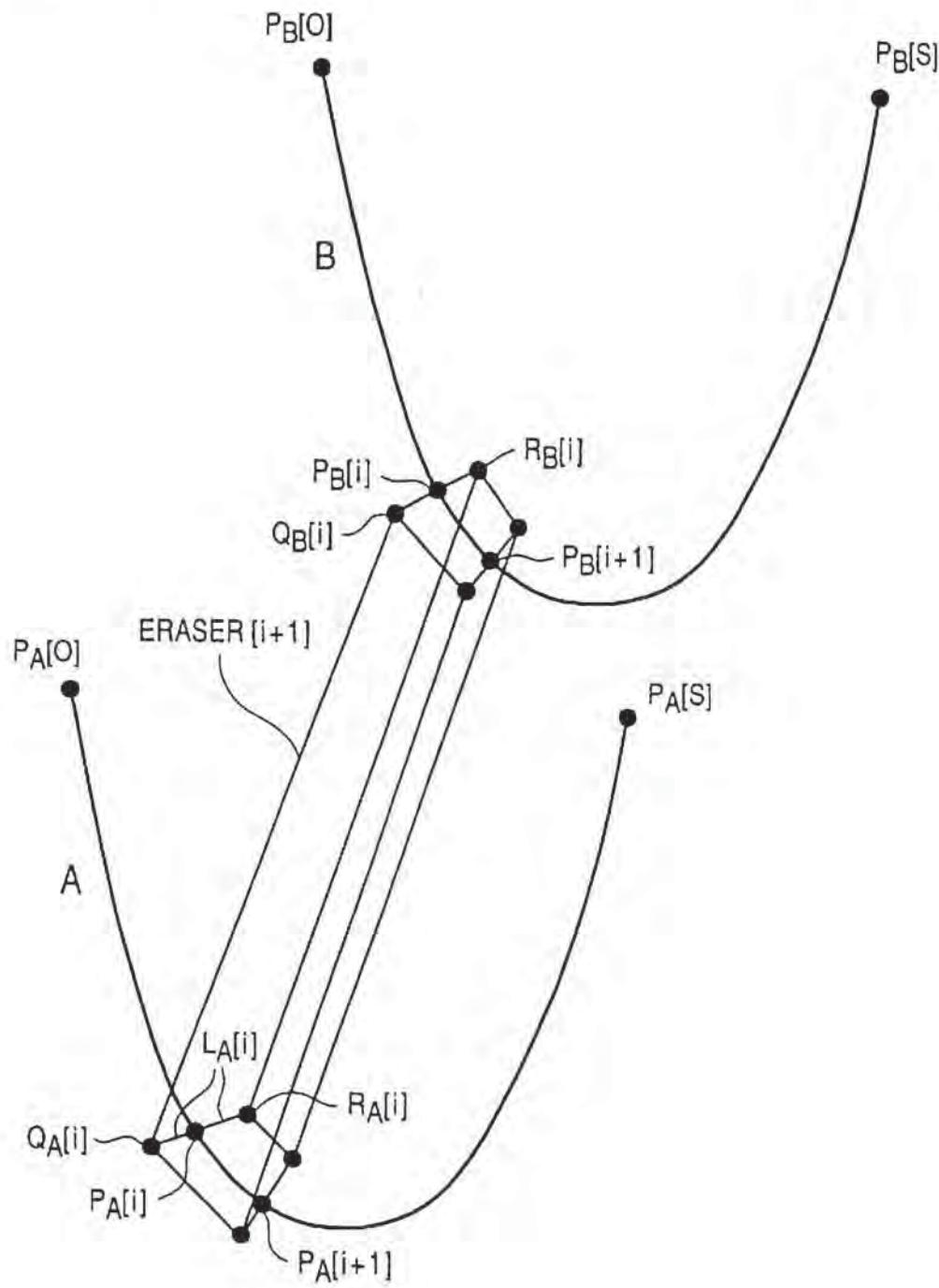


FIG. 4B

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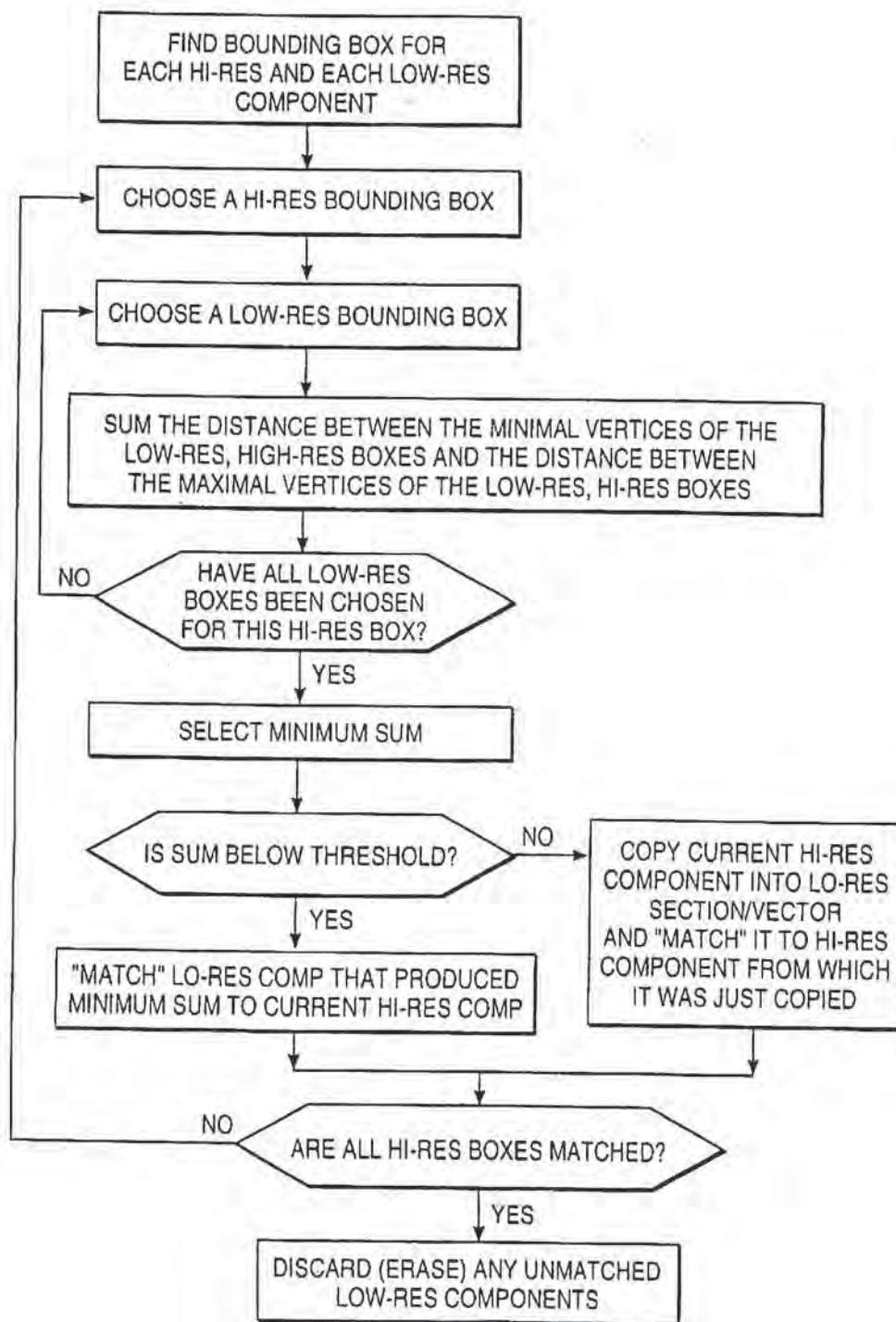


FIG. 5

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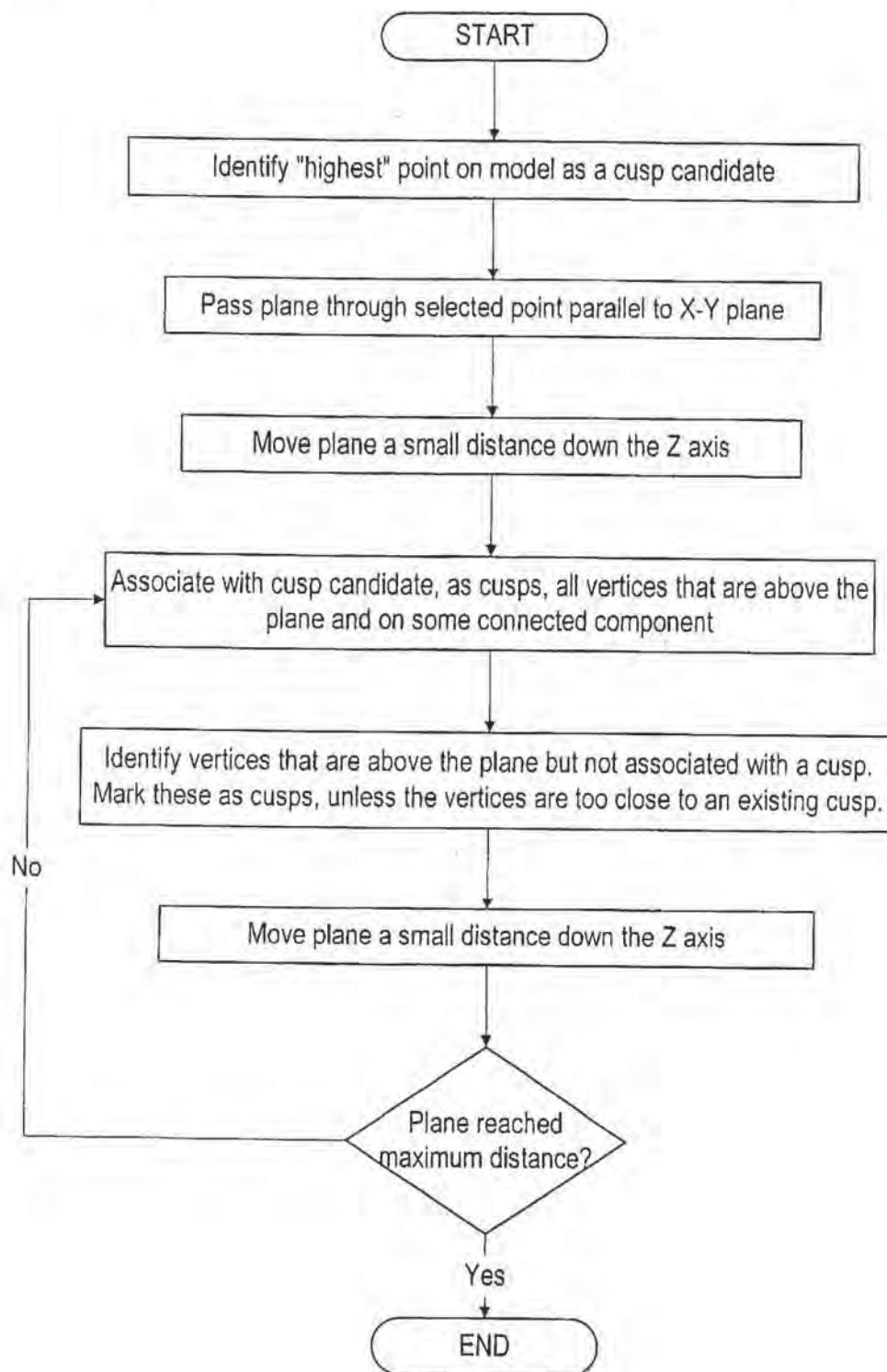


FIG. 6A

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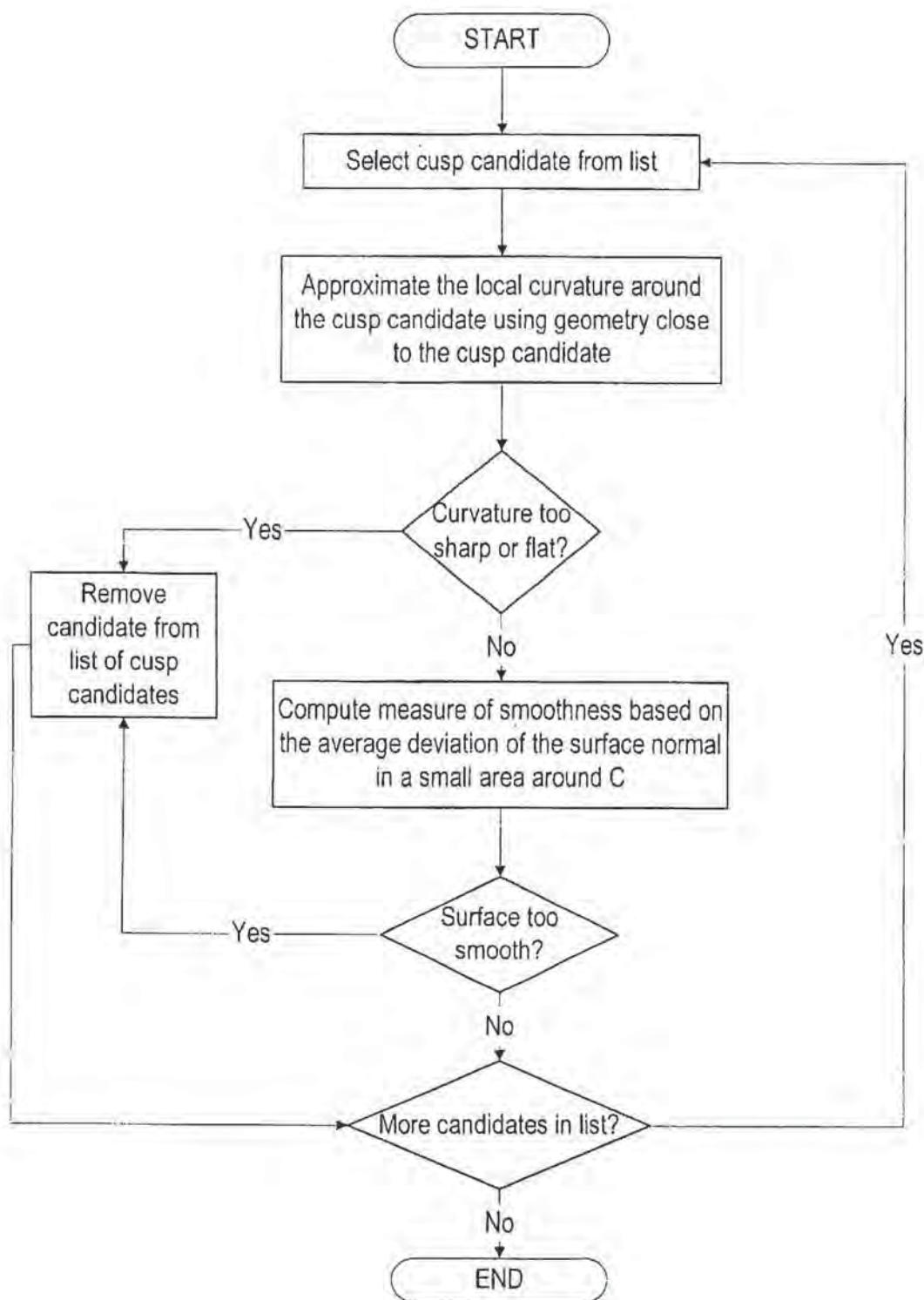


FIG. 6B

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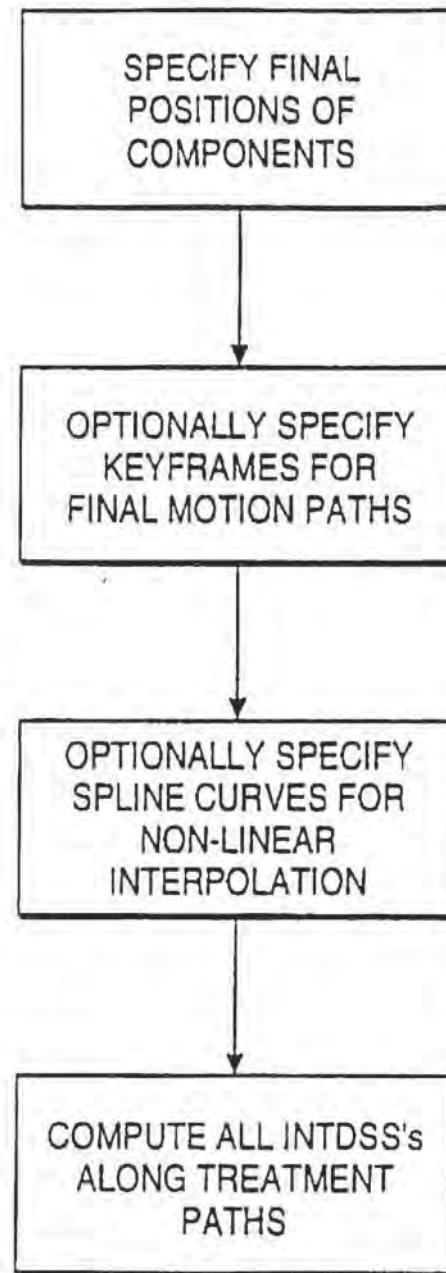


FIG. 7

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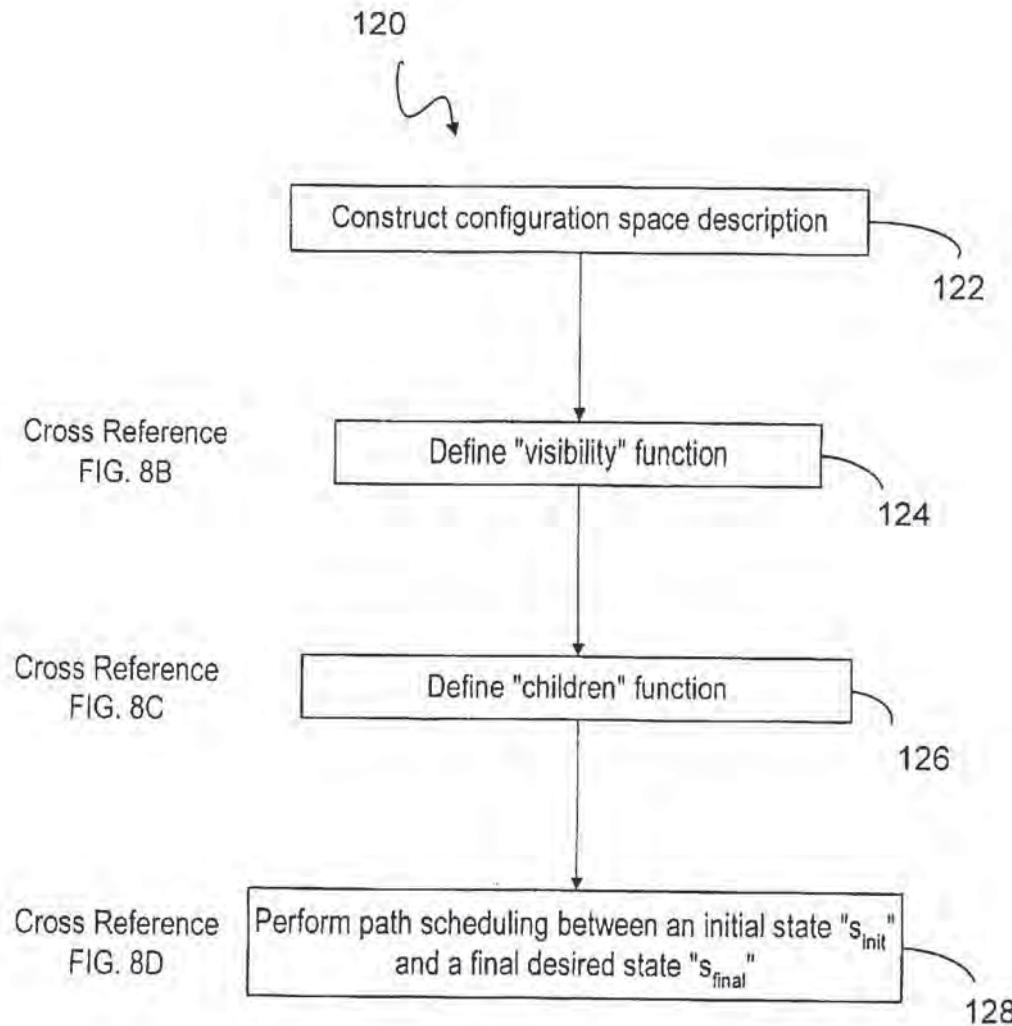


FIG. 8A

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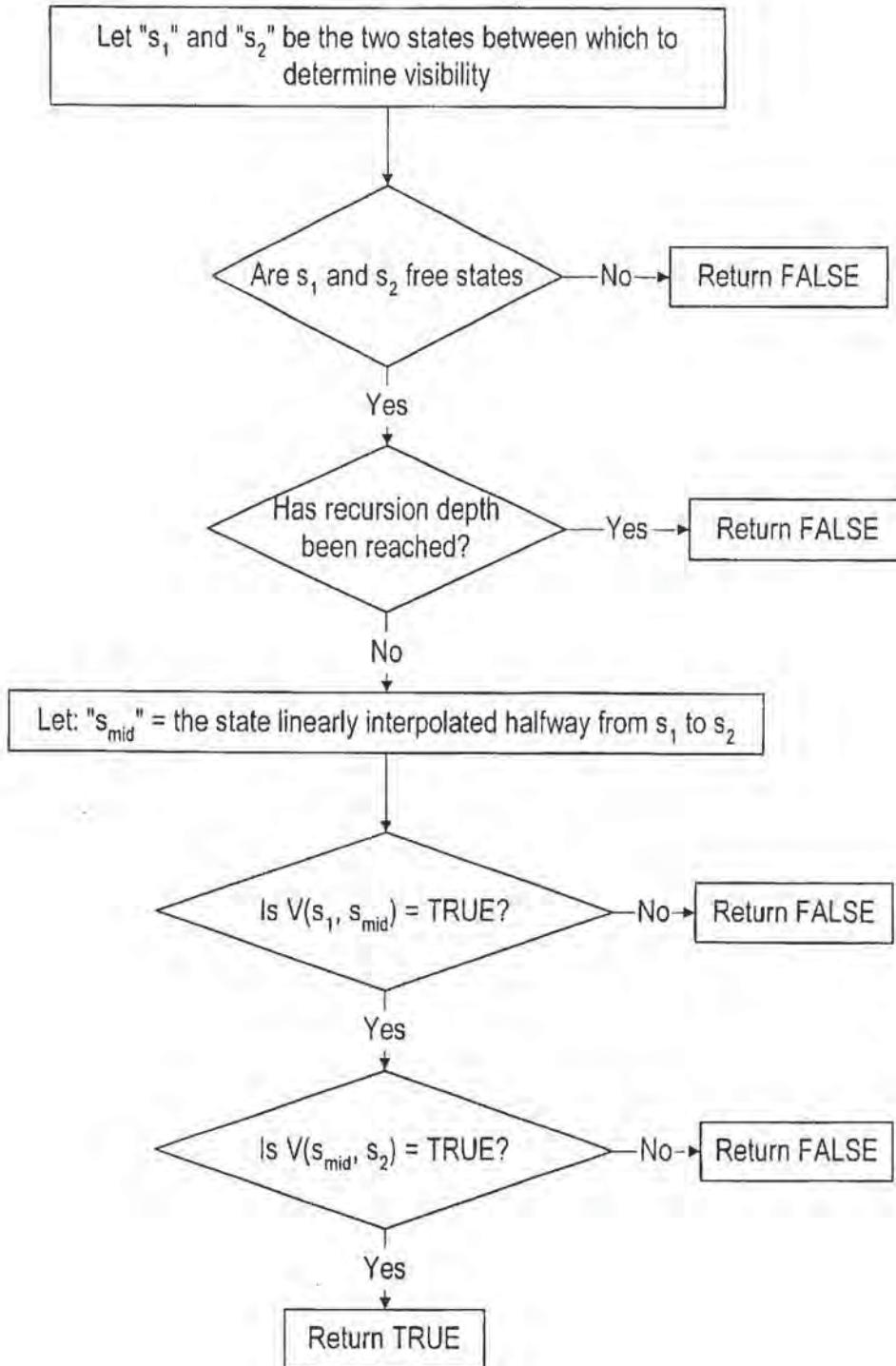


FIG. 8B

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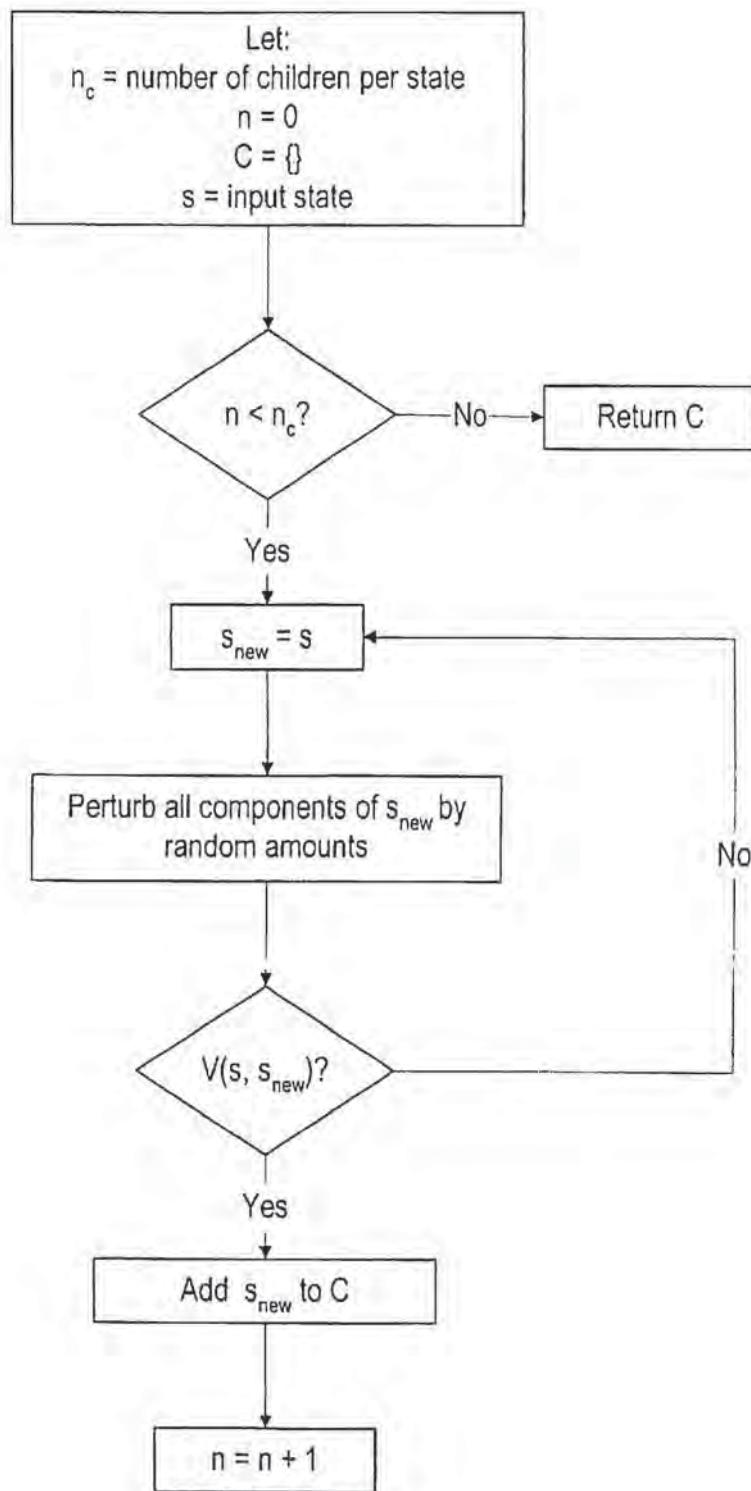


FIG. 8C

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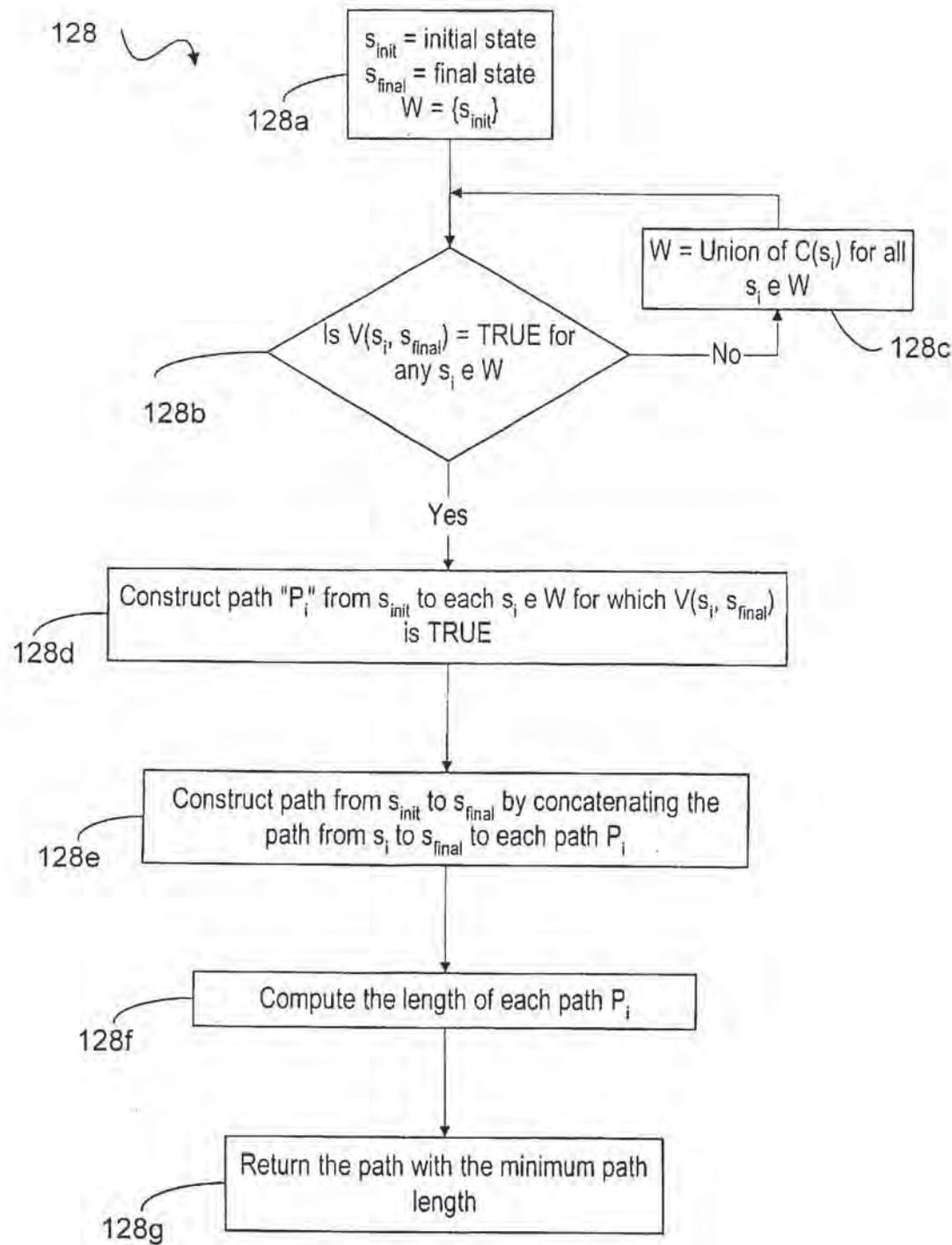


FIG. 8D

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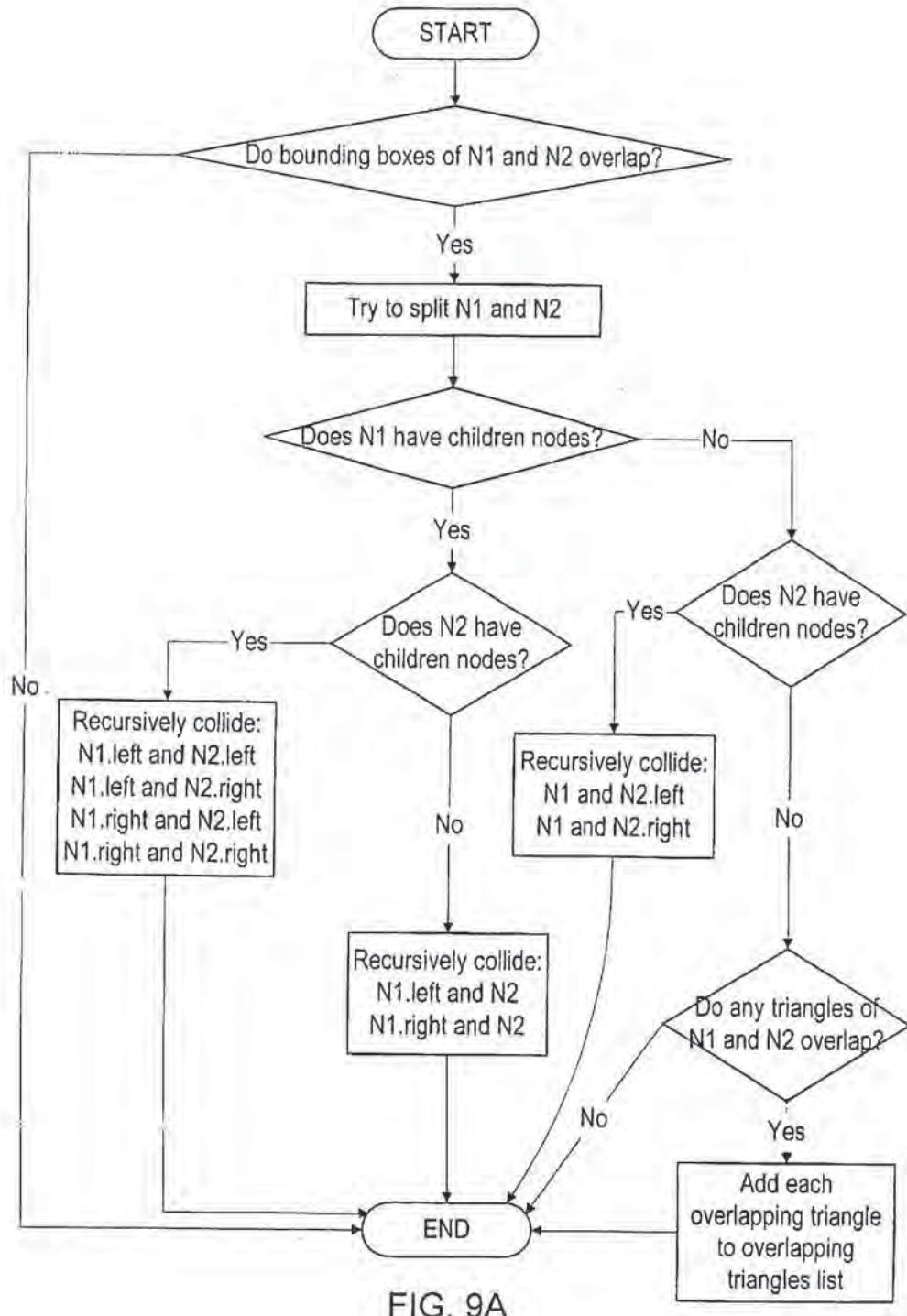


FIG. 9A

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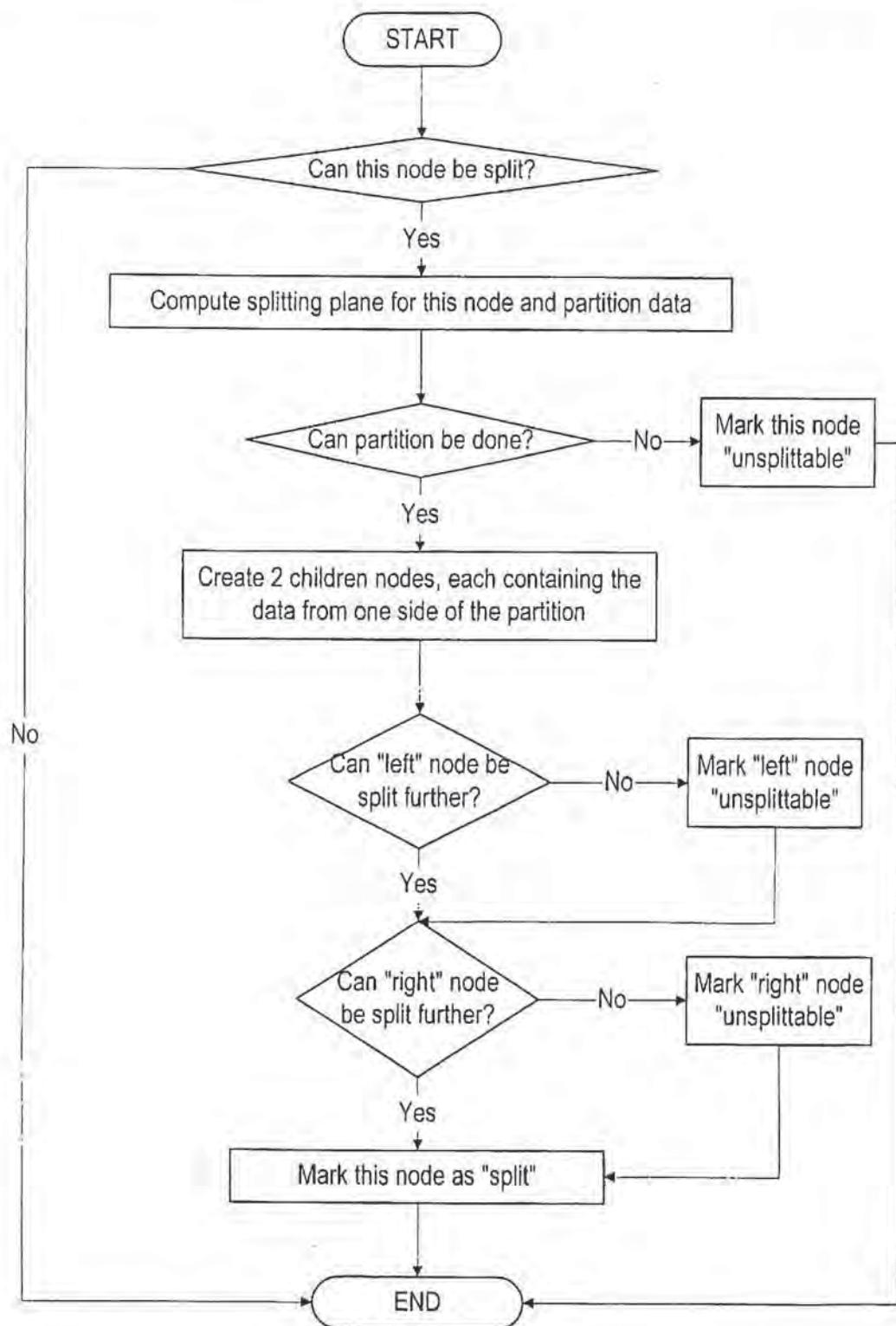


FIG. 9B

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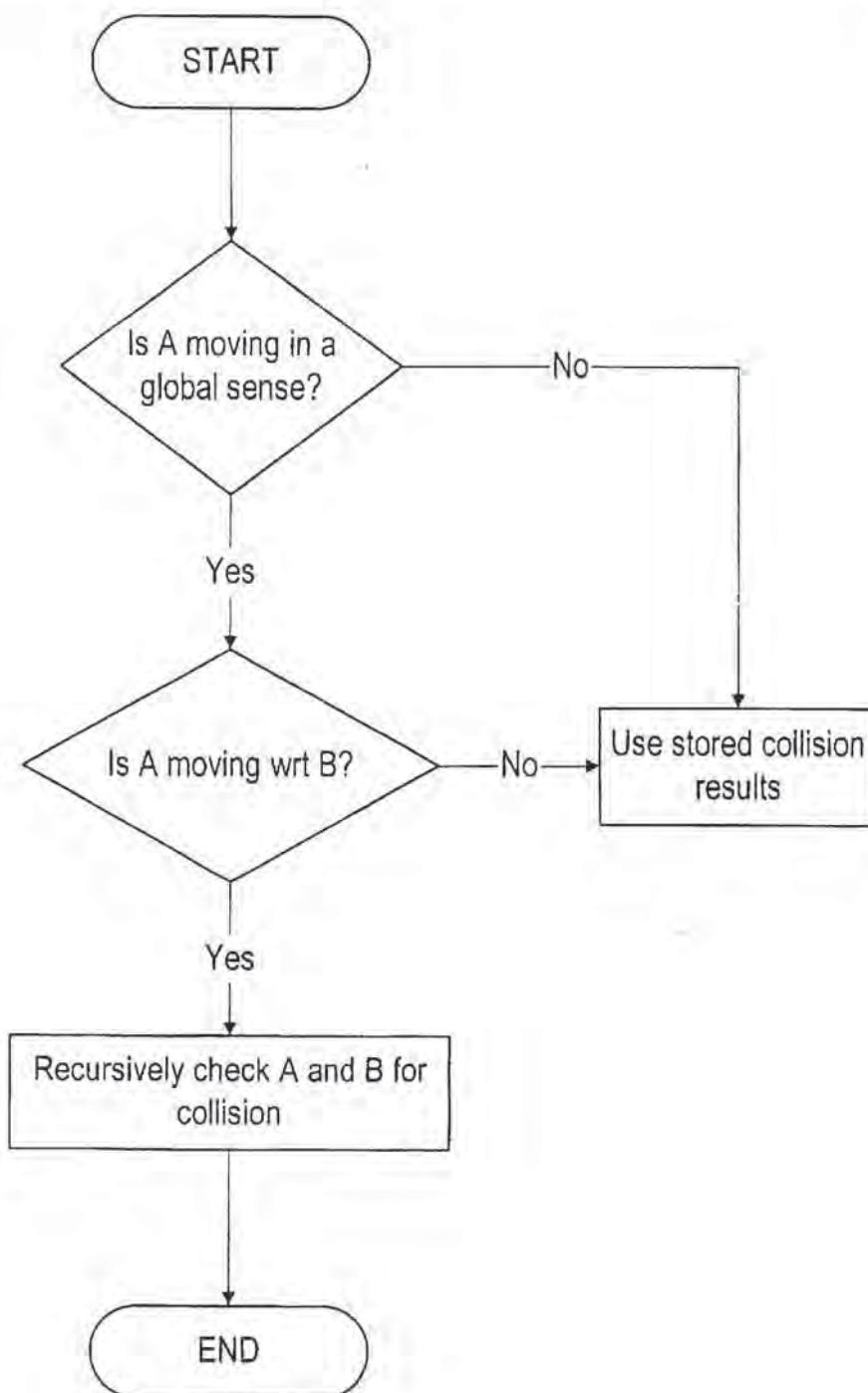


FIG. 9C

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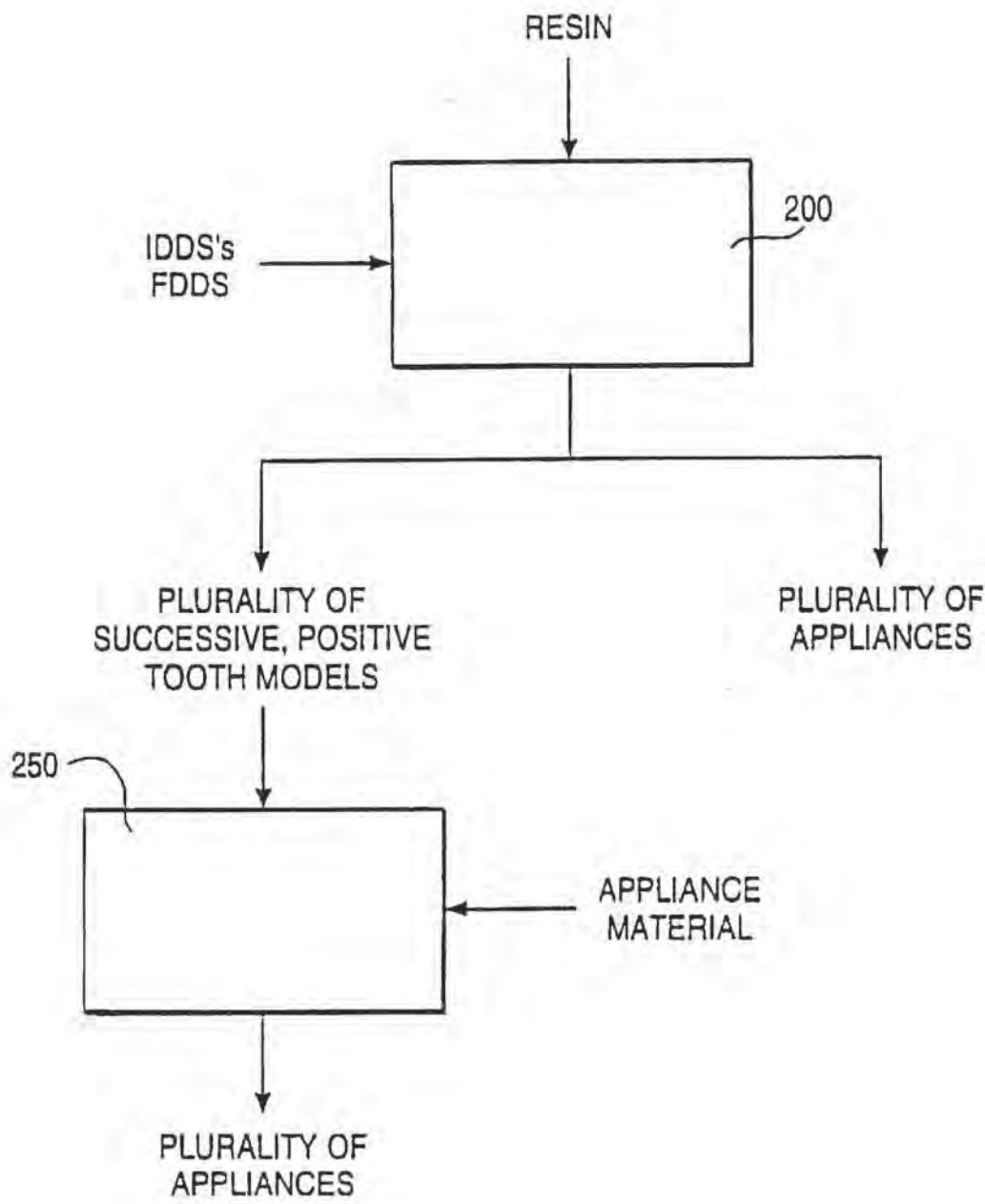


FIG. 10

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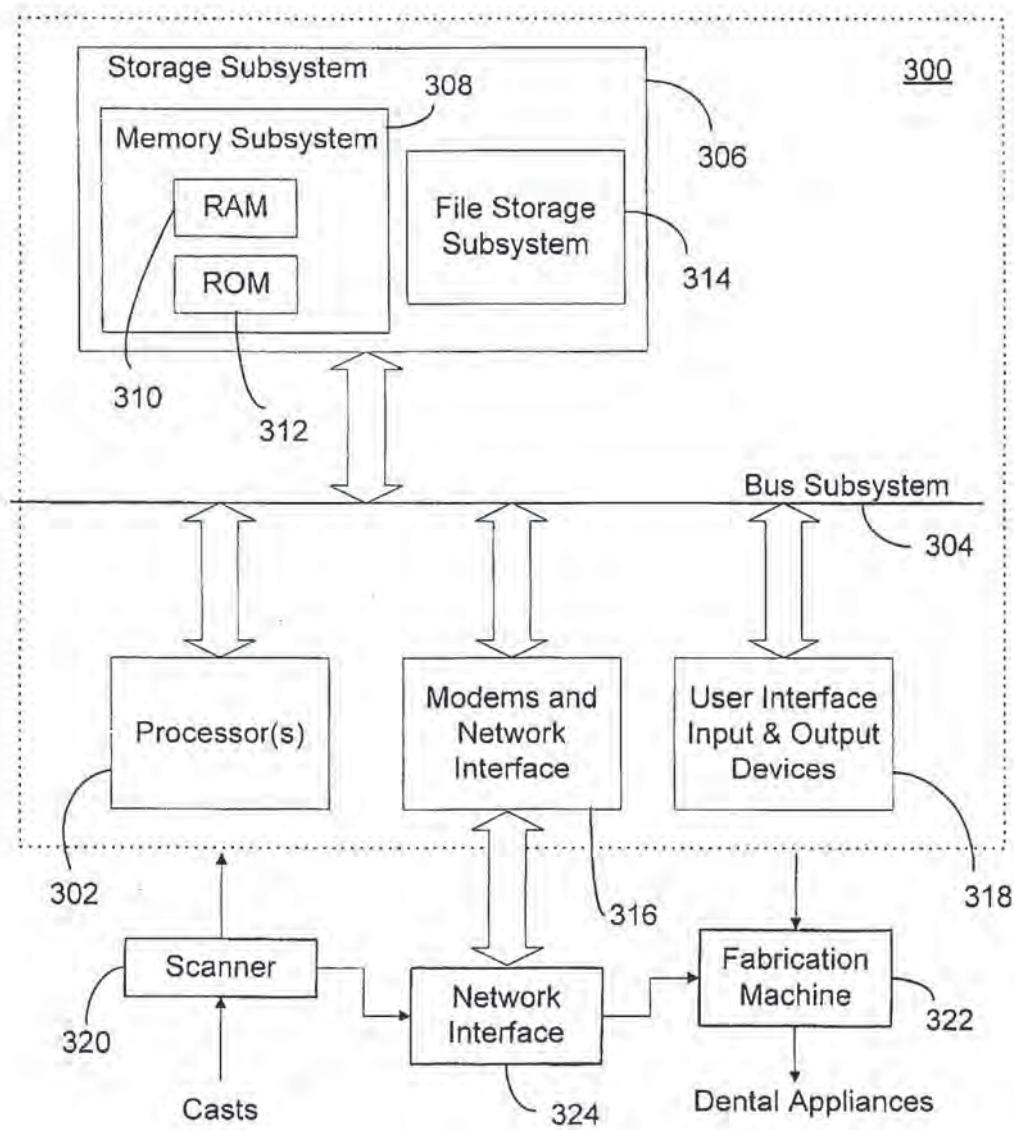


FIG. 11

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**METHOD AND SYSTEM FOR
INCREMENTALLY MOVING TEETH**

**CROSS-REFERENCES TO RELATED
APPLICATIONS**

This application is a continuation of application Ser. No. 09/466,353 filed Dec. 17, 1999 now U.S. Pat. No. 6,398,548, which was a continuation of PCT/US98/12861, filed Jun. 19, 1998, and a continuation-in-part of application Ser. No. 08/947,080, filed on Oct. 8, 1997, now U.S. Pat. No. 5,975,893, which claimed the benefit of provisional application No. 60/050,342, filed Jun. 20, 1997. The full disclosures of each of the above applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is related generally to the field of orthodontics. More particularly, the present invention is related to a method and system for incrementally moving teeth from an initial tooth arrangement to a final tooth arrangement.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically scheduled with the orthodontist, dentist, and/or X-ray laboratory so that X-rays and photographs of the patient's teeth and jaw structure can be taken. Also during this preliminary meeting, or possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well bonded to the teeth.

The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontics as "ligation" and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces

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will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tightening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

2. Description of the Background Art

Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, La. 70125, and Tru-Tain Plastics, Rochester, Minn. 55902. The manufacture of orthodontic positioners is described in U.S. Pat. Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.* 30:673-680; Cureton (1996) *J. Clin. Orthodon.* 30:390-395; Chiappone (1980) *J. Clin. Orthodon.* 14:121-133; Shilliday (1971) *Am. J. Orthodontics* 59:596-599; Wells (1970) *Am. J. Orthodontics* 58:351-366; and Cottingham (1969) *Am. J. Orthodontics* 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics* 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459.

U.S. Pat. Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Pat. Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

BRIEF SUMMARY OF THE INVENTION

The present invention provides improved methods and systems for repositioning teeth from an initial tooth arrange-

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ment to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, certain of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

Systems according to the present invention will include at least a first appliance having a geometry selected to reposition a patient's teeth from the initial tooth arrangement to a first intermediate arrangement where individual teeth will be incrementally repositioned. The system will further comprise at least one intermediate appliance having a geometry selective to progressively reposition teeth from the first intermediate arrangement to one or more successive intermediate arrangements. The system will still further comprise a final appliance having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. In some cases, it will be desirable to form the final appliance or several appliances to "over correct" the final tooth position, as discussed in more detail below.

As will be described in more detail below in connection with the methods of the present invention, the systems may be planned and all individual appliances fabricated at the outset of treatment, and the appliances may thus be provided to the patient as a single package or system. The order in which the appliances are to be used will be clearly marked, (e.g. by sequential numbering) so that the patient can place the appliances over his or her teeth at a frequency prescribed by the orthodontist or other treating professional. Unlike braces, the patient need not visit the treating professional every time an adjustment in the treatment is made. While the patients will usually want to visit their treating professionals periodically to assure that treatment is going according to the original plan, eliminating the need to visit the treating professional each time an adjustment is to be made allows the treatment to be carried out in many more, but smaller,

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successive steps while still reducing the time spent by the treating professional with the individual patient. Moreover, the ability to use polymeric shell appliances which are more comfortable, less visible, and removable by the patient, greatly improves patient compliance, comfort, and satisfaction.

According to a method of the present invention, a patient's teeth are repositioned from an initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment appliances in the patient's mouth. Conveniently, the appliances are not affixed and the patient may place and replace the appliances at any time during the procedure. The first appliance of the series will have a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement. After the first intermediate arrangement is approached or achieved, one or more additional (intermediate) appliances will be successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). The treatment will be finished by placing a final appliance in the patient's mouth, where the final appliance has a geometry selected to progressively reposition teeth from the last intermediate arrangement to the final tooth arrangement. The final appliance or several appliances in the series may have a geometry or geometries selected to over correct the tooth arrangement, i.e. have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e. to permit some movement of individual teeth back toward their pre-corrected positions. Over correction may also be beneficial to speed the rate of correction, i.e. by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, treatment can be terminated before the teeth reach the positions defined by the final appliance or appliances. The method will usually comprise placing at least two additional appliances, often comprising placing at least ten additional appliances, sometimes placing at least twenty-five additional appliances, and occasionally placing at least forty or more additional appliances. Successive appliances will be replaced when the teeth either approach (within a preselected tolerance) or have reached the target end arrangement for that stage of treatment, typically being replaced at an interval in the range from 2 days to 20 days, usually at an interval in the range from 5 days to 10 days.

Often, it may be desirable to replace the appliances at a time before the "end" tooth arrangement of that treatment stage is actually achieved. It will be appreciated that as the teeth are gradually repositioned and approach the geometry defined by a particular appliance, the repositioning force on the individual teeth will diminish greatly. Thus, it may be possible to reduce the overall treatment time by replacing an earlier appliance with the successive appliance at a time when the teeth have been only partially repositioned by the earlier appliance. Thus, the FDDS can actually represent an over correction of the final tooth position. This both speeds the treatment and can offset patient relapse.

In general, the transition to the next appliance can be based on a number of factors. Most simply, the appliances can be replaced on a predetermined schedule or at a fixed time interval (i.e. number of days for each appliance) determined at the outset based on an expected or typical

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patient response. Alternatively, actual patient response can be taken into account, e.g. a patient can advance to the next appliance when that patient no longer perceives pressure on their teeth from a current appliance, i.e. the appliance they have been wearing fits easily over the patient's teeth and the patient experiences little or no pressure or discomfort on his or her teeth. In some cases, for patients whose teeth are responding very quickly, it may be possible for a treating professional to decide to skip one or more intermediate appliances, i.e. reduce the total number of appliances being used below the number determined at the outset. In this way, the overall treatment time for a particular patient can be reduced.

In another aspect, methods of the present invention comprise repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. The present invention provides improvements to such methods which comprise determining at the outset of treatment geometries for at least three of the appliances which are to be worn successively by a patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement. Preferably, at least four geometries will be determined in the outset, often at least ten geometries, frequently at least twenty-five geometries, and sometimes forty or more geometries. Usually, the tooth positions defined by the cavities in each successive geometry differ from those defined by the prior geometry by no more than 2 mm, preferably no more than 1 mm, and often no more than 0.5 mm, as defined above.

In yet another aspect, methods are provided for producing a digital data set representing a final tooth arrangement. The methods comprise providing an initial data set representing an initial tooth arrangement, and presenting a visual image based on the initial data set. The visual image is then manipulated to reposition individual teeth in the visual image. A final digital data set is then produced which represents the final tooth arrangement with repositioned teeth as observed in the visual image. Conveniently, the initial digital data set may be provided by conventional techniques, including digitizing X-ray images, images produced by computer-aided tomography (CAT scans), images produced by magnetic resonance imaging (MRI), and the like. Preferably, the images will be three-dimensional images and digitization may be accomplished using conventional technology. Usually, the initial digital data set is provided by producing a plaster cast of the patient's teeth (prior to treatment) by conventional techniques. The plaster cast so produced may then be scanned using laser or other scanning equipment to produce a high resolution digital representation of the plaster cast of the patient's teeth. Use of the plaster cast is preferred since it does not expose the patient to X-rays or subject the patient to the inconvenience of an MRI scan.

In a preferred embodiment, a wax bite is also obtained from the patient using standard methods. The wax bite allows plaster casts of a patient's upper and lower dentition to be placed relative to one another in the centric occlusal position. The pair of casts are then scanned to provide information on the relative position of the jaw in this position. This information is then incorporated into the IDDS for both arches.

Once the digital data set is acquired, an image can be presented and manipulated on a suitable computer system equipped with computer-aided design software, as described in greater detail below. The image manipulation will usually comprise defining boundaries about at least some of the

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individual teeth, and causing the images of the teeth to be moved relative to the jaw and other teeth by manipulation of the image via the computer. Methods are also provided for detecting cusp information for the teeth. The image manipulation can be done entirely subjectively, i.e. the user may simply reposition teeth in an aesthetically and/or therapeutically desired manner based on observation of the image alone. Alternatively, the computer system could be provided with rules and algorithms which assist the user in repositioning the teeth. In some instances, it will be possible to provide rules and algorithms which reposition the teeth in a fully automatic manner, i.e. without user intervention. Once the individual teeth have been repositioned, a final digital data set representing the desired final tooth arrangement will be generated and stored.

A preferred method for determining the final tooth arrangement is for the treating professional to define the final tooth positions, e.g. by writing a prescription. The use of prescriptions for defining the desired outcomes of orthodontic procedures is well known in the art. When a prescription or other final designation is provided, the image can then be manipulated to match the prescription. In some cases, it would be possible to provide software which could interpret the prescription in order to generate the final image and thus the digital data set representing the final tooth arrangement.

In yet another aspect, methods according to the present invention are provided for producing a plurality of digital data sets representing a series of discrete tooth arrangements progressing from an initial tooth arrangement to a final tooth arrangement. Such methods comprise providing a digital data set representing an initial tooth arrangement (which may be accomplished according to any of the techniques set forth above). A digital data set representing a final tooth arrangement is also provided. Such final digital data set may be determined by the methods described previously. The plurality of successive digital data sets are then produced based on the initial digital data set and the final digital data set. Usually, the successive digital data sets are produced by determining positional differences between selected individual teeth in the initial data set and in the final data set and interpolating said differences. Such interpolation may be performed over as many discrete stages as may be desired, usually at least three, often at least four, more often at least ten, sometimes at least twenty-five, and occasionally forty or more. Many times, the interpolation will be linear interpolation for some or all of the positional differences. Alternatively, the interpolation may be non-linear. In a preferred embodiment, non-linear interpolation is computed automatically by the computer using path scheduling and collision detection techniques to avoid interferences between individual teeth. The positional differences will correspond to tooth movements where the maximum linear movement of any point on a tooth is 2 mm or less, usually being 1 mm or less, and often being 0.5 mm or less.

Often, the user will specify certain target intermediate tooth arrangements, referred to as "key frames," which are incorporated directly into the intermediate digital data sets. The methods of the present invention then determine successive digital data sets between the key frames in the manner described above, e.g. by linear or non-linear interpolation between the key frames. The key frames may be determined by a user, e.g. the individual manipulating a visual image at the computer used for generating the digital data sets, or alternatively may be provided by the treating professional as a prescription in the same manner as the prescription for the final tooth arrangement.

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In still another aspect, methods according to the present invention provide for fabricating a plurality of dental incremental position adjustment appliances. Said methods comprise providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements, generally as just described. The dental appliances are then fabricated based on at least some of the digital data sets representing the successive tooth arrangements. Preferably, the fabricating step comprises controlling a fabrication machine based on the successive digital data sets to produce successive positive models of the desired tooth arrangements. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. The fabrication machine may comprise a stereolithography or other similar machine which relies on selectively hardening a volume of non-hardened polymeric resin by scanning a laser to selectively harden the resin in a shape based on the digital data set. Other fabrication machines which could be utilized in the methods of the present invention include tooling machines and wax deposition machines.

In still another aspect, methods of the present invention for fabricating a dental appliance comprise providing a digital data set representing a modified tooth arrangement for a patient. A fabrication machine is then used to produce a positive model of the modified tooth arrangement based on the digital data set. The dental appliance is then produced as a negative of the positive model. The fabrication machine may be a stereolithography or other machine as described above, and the positive model is produced by conventional pressure or vacuum molding techniques.

In a still further aspect, methods for fabricating a dental appliance according to the present invention comprise providing a first digital data set representing a modified tooth arrangement for a patient. A second digital data set is then produced from the first digital data set, where the second data set represents a negative model of the modified tooth arrangement. The fabrication machine is then controlled based on the second digital data set to produce the dental appliance. The fabrication machine will usually rely on selectively hardening a non-hardened resin to produce the appliance. The appliance typically comprises a polymeric shell having a cavity shape to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

FIG. 1B illustrates a single tooth from FIG. 1A and defines how tooth movement distances are determined.

FIG. 1C illustrates the jaw of FIG. 1A together with an incremental position adjustment appliance which has been configured according to the methods of the present invention.

FIG. 2 is a block diagram illustrating the steps of the present invention for producing a system of incremental position adjustment appliances.

FIG. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

FIG. 4A is a flow chart illustrating an eraser tool for the methods herein.

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FIG. 4B illustrates the volume of space which is being erased by the program of FIG. 4A.

FIG. 5 is a flow chart illustrating a program for matching high-resolution and low-resolution components in the manipulation of data sets of FIG. 3.

FIG. 6A is a flow chart illustrating a program for performing the "detection" stage of the cusp detection algorithm.

FIG. 6B is a flow chart illustrating a program for performing the "rejection" stage of the cusp detection algorithm.

FIG. 7 illustrates the method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances of the present invention.

FIG. 8A is a flow chart illustrating the steps performed by the path scheduling algorithm.

FIG. 8B is a flow chart illustrating the steps for performing the "visibility" function according to one embodiment of the present invention.

FIG. 8C is a flow chart illustrating the steps for performing the "children" function according to one embodiment of the present invention.

FIG. 8D is a flow chart illustrating the steps for performing path scheduling step 128 of FIG. 8A.

FIG. 9A is a flow chart illustrating the steps for performing recursive collision testing during collision detection.

FIG. 9B is a flow chart illustrating node splitting performed during collision detection according to an embodiment of the present invention.

FIG. 9C is a flow chart illustrating steps for providing additional motion information to the collision detection process.

FIG. 10 illustrates alternative processes for producing a plurality of appliances according to the methods of the present invention utilizing digital data sets representing the intermediate and final appliance designs.

FIG. 11 is a simplified block diagram of a data processing system incorporating an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

According to the present invention, systems and methods are provided for incrementally moving teeth using a plurality of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

Referring now to FIG. 1A, a representative jaw 100 includes sixteen teeth 102. The present invention is intended to move at least some of these teeth from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this centerline (CL), the teeth may be moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally, the tooth may be rotated about the centerline, as represented by arrow

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114. Thus, all possible free-form motions of the tooth can be performed. Referring now to FIG. 1B, the magnitude of any tooth movement achieved by the methods and devices of the present invention will be defined in terms of the maximum linear translation of any point P on a tooth 102. Each point P_i will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in FIG. 1A. That is, while the point will usually follow a non-linear path, there will be a linear distance between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P₁ may in fact undergo a true side-to-side translation as indicated by arrow d₁, while a second arbitrary point P₂ may travel along an arcuate path, resulting in a final translation d₂. Many aspects of the present invention are defined in terms of the maximum permissible movement of a point P_i induced by the methods in any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point P_i on the tooth which undergoes the maximum movement for that tooth in any treatment step.

Referring now to FIG. 1C, systems according to the present invention will comprise a plurality of incremental position adjustment appliances. The appliances are intended to effect incremental repositioning of individual teeth in the jaw as described generally above. In a broadest sense, the methods of the present invention can employ any of the known positioners, retainers, or other removable appliances which are known for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. The systems of the present invention, in contrast with prior apparatus and systems, will provide a plurality of such appliances intended to be worn by a patient successively in order to achieve the gradual tooth repositioning as described herein. A preferred appliance 100 will comprise a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to a successive tooth arrangement. The polymeric shell will preferably, but not necessarily, fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others of the teeth will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, many or most of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance. Additionally, the gums and/or the palette can serve as an anchor region, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

The polymeric appliance 100 of FIG. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, Tru-Tain Plastics, Rochester, Minn. 55902. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor. Specific methods for producing the appliances 100 are described hereinafter.

Referring now to FIG. 2, the overall method of the present invention for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the IDDS. The IDDS may be

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obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, magnetic resonance images, etc. Methods for digitizing such conventional images to produce data sets useful in the present invention are well known and described in the patent and medical literature. Usually, however, the present invention will rely on first obtaining a plaster cast of the patient's teeth by well known techniques, such as those described in Graber, *Orthodontics: Principle and Practice*, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415. After the tooth casting is obtained, it can be digitally scanned using a conventional laser scanner or other range acquisition system to produce the IDDS. The data set produced by the range acquisition system may, of course, be converted to other formats to be compatible with the software which is used for manipulating images within the data set, as described in more detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Pat. No. 5,605,459, the full disclosure of which is incorporated herein by reference.

There are a variety of range acquisition systems, generally categorized by whether the process of acquisition requires contact with the three dimensional object. A contact-type range acquisition system utilizes a probe, having multiple degrees of translational and/or rotational freedom. By recording the physical displacement of the probe as it is drawn across the sample surface, a computer-readable representation of the sample object is made. A non-contact-type range acquisition device can be either a reflective-type or transmissive-type system. There are a variety of reflective systems in use. Some of these reflective systems utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Those non-contact-type systems working by reflected optical energy further contain special instrumentation configured to permit certain measuring techniques to be performed (e.g., imaging radar, triangulation and interferometry).

A preferred range acquisition system is an optical, reflective, non-contact-type scanner. Non-contact-type scanners are preferred because they are inherently nondestructive (i.e., do not damage the sample object), are generally characterized by a higher capture resolution and scan a sample in a relatively short period of time. One such scanner is the Cyberware Model 15 manufactured by Cyberware, Inc., Monterey, Calif.

Either non-contact-type or contact-type scanners may also include a color camera, that when synchronized with the scanning capabilities, provides a means for capturing, in digital format, a color representation of the sample object. The importance of this further ability to capture not just the shape of the sample object but also its color is discussed below.

In a preferred embodiment, a wax bite is also obtained from a patient. The wax bite enables scanning of the relative positions of the upper and lower dentition in centric occlusion. This is usually accomplished by first placing the lower cast in front of the scanner, with the teeth facing upwards, then placing the wax bite on top of the lower cast, and finally by placing the upper cast on top of the lower cast, with the teeth downwards, resting on the wax bite. A cylindrical scan is then acquired for the lower and upper casts in their relative positions. The scanned data provides a digital model of medium resolution representing an object which is the combination of the patient's arches positioned in the same relative configuration as in the mouth.

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The digital model acts as a template guiding the placement of the two individual digital models (one per arch). More precisely, using software, for example the CyberWare alignment software, each digital arch is in turn aligned to the pair scan. The individual models are then positioned relative to each other corresponding to the arches in the patient's mouth.

The methods of the present invention will rely on manipulating the IDDS at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. While the methods will rely on computer manipulation of digital data, the systems of the present invention comprising multiple dental appliances having incrementally differing geometries may be produced by non-computer-aided techniques. For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques. While such manual creation of the appliance systems of the present invention will generally be much less preferred, systems so produced will come within the scope of the present invention.

Referring again to FIG. 2, after the IDDS has been obtained, the digital information will be introduced to the computer or other workstation for manipulation. In the preferred approach, individual teeth and other components will be "cut" to permit their individual repositioning or removal from the digital data. After thus "freeing" the components, the user will often follow a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition them based on the visual appearance or using rules and algorithms programmed into the computer. Once the user is satisfied with the final arrangement, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDDS's, as described in more detail below.

FIG. 3 illustrates a representative technique for manipulating the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner will be in a high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data set representing the IDDS at a lower resolution will be created. The user will manipulate the lower resolution images while the computer will update the high resolution data set as necessary. The user can also view/manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS will also be converted into a quad edge data structure if not already present in that form. A quad edge data structure is a standard topological data structure defined in *Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams*, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and

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other oral tissue, the user will usually delete structure which is unnecessary for image manipulation and/or final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI. Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and/or which teeth will be extracted. Shaving allows the patient to maintain their teeth when only a small amount of space is needed. Typically, extraction and shaving, of course, will be utilized in the treatment planning only when the actual patient teeth are to be extracted and/or shaved prior to initiating repositioning according to the methods of the present invention.

Removing unwanted and/or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and instructs the software to erase the unwanted section, all triangles within the box set by the user will be removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of the box. The holes created in the model at the faces of the box are re-triangulated and closed using the newly created vertices.

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the tooth or other component images independent of remaining portions of the model. In one embodiment, the saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes, either open or closed. A set of lines connects the two curves and shows the user the general cutting path. The user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

In an alternate preferred embodiment, the teeth are separated by using the saw as a "coring" device, cutting the tooth from above with vertical saw cuts. The crown of the tooth, as well as the gingivae tissue immediately below the crown are separated from the rest of the geometry, and treated as an individual unit, referred to as a tooth. When this model is moved, the gingivae tissue moves relative to the crown, creating a first order approximation of the way that the gingivae will reform within a patient's mouth.

Each tooth may also be separated from the original trimmed model. Additionally, a base may be created from the original trimmed model by cutting off the crowns of the teeth. The resulting model is used as a base for moving the teeth. This facilitates the eventual manufacture of a physical mold from the geometric model, as described below.

Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However,

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the user may want to make a thicker cut, for example, when shaving down surrounding teeth, as described above. Graphically, the cut appears as a curve bounded by the thickness of the cut on one side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear approximation of the Saw Tool's curve path. The user chooses the number of erasers, which determines the sophistication of the curve created—the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline curves. Once a saw cut has been completely specified the user applies the cut to the model. The cut is performed as a sequence of erasings. A preferred algorithm is set forth in FIG. 4A. FIG. 4B shows a single erasing iteration of the cut as described in the algorithm for a open ended B-spline curve. For a vertical cut, the curves are closed with $P_A[O]$ and $P_A[S]$ the same point and $P_B[O]$ and $P_B[S]$ being the same point.

In one embodiment, the software may automatically partition the saw tool into a set of erasers based upon a smoothness measure input by the user. The saw is adaptively subdivided until an error metric measures the deviation from the ideal representation to the approximate representation to be less than a threshold specified by the smoothness setting. The preferred error metric used compares the linear length of the subdivided curve to the arclength of the ideal spline curve. When the difference is greater than a threshold computed from the smoothness setting, a subdivision point is added along the spline curve.

A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

After the user has completed all desired cutting operations with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components. The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. The algorithm is described in FIG. 5.

Cusp detection: In a preferred embodiment, the software provides the ability to detect cusps for a tooth. Cusps are pointed projections on the chewing surface of a tooth. Cusp detection can be performed either before or after the cutting phase has been performed. The algorithm used for cusp detection is composed of two stages: (1) "detection" stage, during which a set of points on the tooth are determined as candidates for cusp locations; and (2) "rejection" stage, during which candidates from the set of points are rejected if they do not satisfy a set of criteria associated with cusps.

A preferred algorithm for the "detection" stage is set forth in FIG. 6A. In the detection stage, a possible cusp is viewed

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as an "island" on the surface of the tooth, with the candidate cusp at the highest point on the island. "Highest" is measured with respect to the coordinate system of the model, but could just as easily be measured with respect to the local coordinate system of each tooth if detection is performed after the cutting phase of treatment.

The set of all possible cusps is determined by looking for all local maxima on the tooth model that are within a specified distance of the top of the bounding box of the model. First, the highest point on the model is designated as the first candidate cusp. A plane is passed through this point, perpendicular to the direction along which the height of a point is measured. The plane is then lowered by a small predetermined distance along the Z axis. Next, all vertices connected to the tooth and which are above the plane and on some connected component are associated with the candidate cusp as cusps. This step is also referred to as the "flood fill" step. From each candidate cusp point, outward "flooding" is performed, marking each vertex on the model visited in this manner as "part of" the corresponding candidate cusp. After the flood fill step is complete, every vertex on the model is examined. Any vertex that is above the plane and has not been visited by one of the flood fills is added to the list of candidate cusps. These steps are repeated until the plane is traveled a specified distance.

While this iterative approach can be more time consuming than a local maximum search, the approach described above leads to a shorter list of candidate cusps. Since the plane is lowered a finite distance at each step, very small local maxima that can occur due to noisy data are skipped over.

After the "detection" stage, the cusp detection algorithm proceeds with the "rejection" stage. A preferred algorithm for the "rejection" stage is set forth in FIG. 6B. In this stage, the local geometries around each of cusp candidates are analyzed to determine if they possess "non-cusp-like features." Cusp candidates that exhibit "non-cusp-like features" are removed from the list of cusp candidates.

Various criteria may be used to identify "non-cusp-like features." According to one test, the local curvature of the surface around the cusp candidate is used to determine whether the candidate possesses non-cusp-like features. As depicted in FIG. 6B, the local curvature of the surface around the cusp candidate is approximated, and then analyzed to determine if it is too large (very pointy surface) or too small (very flat surface), in which case the candidate is removed from the list of cusp candidates. Conservative values are used for the minimum and maximum curvatures values to ensure that genuine cusps are not rejected by mistake.

According to an alternate test, a measure of smoothness is computed based on the average normal in an area around the candidate cusp. If the average normal deviates from the normal at the cusp by more than a specified amount, the candidate cusp is rejected. In a preferred embodiment, the deviation of a normal vector N from the cusp normal CN is approximated by the formula:

$$1 - \text{Abs}(N^*CN), \text{ which is zero at no deviation, and 1 when } N \text{ and } CN \text{ are perpendicular.}$$

Once the teeth have been separated, the FDDS can be created from the IDDS. The FDDS is created by following the orthodontists prescription, moving the teeth into their final prescription. In one embodiment, the prescription is entered into a computer, which algorithmically computes the final position of the teeth. In alternate embodiments, a user may move the teeth into their final positions by independently manipulating one or more teeth while satisfying the

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constraints of the prescription. It should be appreciated that various combinations of the above described techniques may also be used to arrive at the final teeth position.

The preferred method for creating the FDDS involves moving the teeth in a specified sequence. First, the centers of each of the teeth are aligned to a standard arch. Then, the teeth are rotated until their roots are in the proper vertical position. Next, the teeth are rotated around their vertical axis into the proper orientation. The teeth are then observed from the side, and translated vertically into their proper vertical position. Finally, the two arches are placed together, and the teeth moved slightly to ensure that the upper and lower arches properly mesh together. The meshing of the upper and lower arches together is visualized using the collision detection algorithm to highlight the contacting points of the teeth in red.

After the teeth and other components have been placed or removed so that the final tooth arrangement has been produced, it is necessary to generate a treatment plan, as illustrated in FIG. 7. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes. For example, it may be desirable to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit the tooth to be manipulated in a manner that requires the anchor, e.g. lifted relative to the jaw.

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous structure in order to permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances. The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path as well as the teeth and other components. The preferred method of separating the teeth using vertical coring, as described above, removes the need for most of these "wax patches".

In the manufacturing process, which relies on generation of positive models to produce the repositioning appliance, adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and the appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been added to the mold. When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which

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engages an anchor placed on the teeth in order to move the tooth in directions which could not otherwise be accomplished.

In addition to such wax patches, an individual component, usually a tooth, can be scaled to a smaller or larger size which will result in a manufactured appliance having a tighter or looser fit, respectively.

Treatment planning is extremely flexible in defining the movement of teeth and other components. The user may change the number of treatment stages, as well as individually control the path and speed of components.

Number of Treatment Stages: The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

Key frames: The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). Unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the initial position, all key frame positions, and the target position). For example, if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position. If the user specifies two key frames for that component, it will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, possibly in yet a different direction, linearly to the target position.

The user can also specify non-linear interpolation between the key frames. A spline curve is used to specify the interpolating function in a conventional manner.

These operations may be done independently to each component, so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between stages 3 and 8, while another moves linearly from stage 1 to 5, and then changes direction suddenly and slows down along a linear path to stage 10. This flexibility allows a great deal of freedom in planning a patient's treatment.

In one embodiment, the software automatically determines the treatment path, based upon the IDDS and the FDDS. This is usually accomplished using a path scheduling algorithm which determines the rate at which each component, i.e. a tooth, moves along a straight path from the initial position to the final position. The path scheduling algorithm used by the present invention determines the treatment path while avoiding "round-tripping" which is the term used by orthodontists referring to moving a tooth along a distance greater than absolutely necessary to straighten the teeth. Such motion is highly undesirable, and has potential negative side effects on the patient. In order to avoid "round-tripping", the path scheduling algorithm schedules or stages the movements of all the teeth by constraining them to the shortest straight-line path between the initial and final position, while avoiding all interferences between separate teeth.

The path scheduling algorithm utilizes a randomized search technique to find an unobstructed path through a configuration space which describes possible treatment

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plans. A preferred embodiment of the algorithm for scheduling motion between two user defined global keyframes is described below. Scheduling over a time interval which includes intermediate keyframes is accomplished by dividing the time interval into subintervals which do not include intermediate keyframes, scheduling each of these intervals independently, and then concatenating the resulting schedules.

Flow chart 120 in FIG. 8A depicts a simplified path scheduling algorithm according to one embodiment of the present invention. As shown in FIG. 8A, first step 122 involves construction of the "configuration space" description. A "configuration," in this context, refers to a given set of positions of all the teeth being considered for movement. Each of these positions may be described in multiple ways. In a preferred embodiment of the present invention, the positions are described by one affine transformation to specify change in location and one rotational transformation to specify the change in orientation of a tooth from its initial position to its final position. The intermediate positions of each tooth are described by a pair of numbers which specify how far to interpolate the location and orientation between the two endpoints. A "configuration" thus consists of two numbers for each tooth being moved, and the "configuration space" refers to the space of all such number pairs. Thus, the configuration space is a Cartesian space, any location in which can be interpreted as specifying the positions of all teeth.

The affine transformation describing the movement of each tooth from its starting position to its ending position is decomposed into translational and rotational components; these transformations are independently interpolated with scalar parameters which are considered two dimensions of the configuration space. The entire configuration space thus consists of two dimensions per moved tooth, all of which are treated equivalently during the subsequent search.

The configuration space is made of "free space" and "obstructed space." "Free" configurations are those which represent valid, physically realizable positions of teeth, while "obstructed" configurations are those which do not. To determine whether a configuration is free or obstructed, a model is created for the positions of the teeth which the configuration describes. A collision detection algorithm is then applied to determine if any of the geometries describing the tooth surfaces intersect. If there are no obstructions, the space is considered free; otherwise it is obstructed. The collision detect algorithm is discussed below in more detail.

At step 124, a "visibility" function $V(s_1, s_2)$ is defined which takes two vectors in the configuration space, " s_1 " and " s_2 ", as input and returns a true or false boolean value. The visibility function returns a true value if and only if a straight line path connecting s_1 and s_2 passes entirely through a free and unobstructed region of the configuration space. A preferred algorithm for the visibility function is set forth in FIG. 8B. The visibility function is approximately computed by testing the teeth model for interferences at discretely sampled points along the line s_1-s_2 . Techniques, such as early termination on failure or choosing the order of sample points by recursively subdividing the interval to be tested, may be used to increase the efficiency of the visibility function.

At step 126 of FIG. 8A, a "children" function $C(s)$ is defined whose input parameter, " s ", is a vector in the configuration space and which returns a set of vectors, " s_c " in the configuration space. FIG. 8C depicts a simplified flow chart illustrating the steps followed for computing children function $C(s)$. Each vector within set s_c satisfies the property

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that $V(s, s_c)$ is true and that each of its components are greater than or equal to the corresponding component of " s ." This implies that any state represented by such a vector is reachable from " s " without encountering any interferences and without performing any motion which is not in the direction prescribed by treatment. Each vector of set " s_c " is created by perturbing each component of " s " by some random, positive amount. The visibility function $V(s, s_c)$ is then computed and " s_c " added to the set " s_c " if the visibility function returns a true boolean value. Additionally, for each such vector generated, a pointer to its parent " s " is recorded for later use.

After the configuration space has been defined, at step 128, path scheduling is performed between an initial state " s_{init} " and a final state " s_{final} ". FIG. 8D depicts a preferred flow chart for performing step 128 depicted in FIG. 8A. As illustrated in FIG. 8D, at step 128a, a set of states "W" is defined to initially contain only the initial state s_{init} . Next, at step 128b, the visibility function is invoked to determine if $V(s, s_{final})$ is true for at least one state s_i in W. If the visibility function returns a false boolean value, at step 128c, the set of states "W" is replaced with the union of $C(s_i)$ for all s_i in W. Steps 128b and 128c are repeated until $V(s_i, s_{final})$ returns a true boolean value for any s_i belonging to W.

At step 128d, for each s_i for which $V(s_i, s_{final})$ is true, an unobstructed path P_i is constructed from s_i to s_{init} by following the parent pointers back to s_{init} . At step 128e, the path from s_{init} to s_{final} is then constructed by concatenating the paths P_i with the final step from S_i to s_{final} . If there are multiple paths from s_{init} to s_{final} , the total length of each path is computed at step 128f. Finally, at step 128g, the path with the shortest length is then chosen as the final path. The length of the chosen path corresponds to the total time and stages required for a treatment plan.

The resulting final path consists of a series of vectors, each of which represents a group of values of the interpolation parameters of the translational and rotational components of the transformations of the moving teeth. Taken together, these constitute a schedule of tooth movement which avoids tooth-to-tooth interferences.

Collision detect algorithm: The collision or interference detection algorithm employed by the present invention is based on the algorithm described in SIGGRAPH article, Stefan Gottschalk et al. (1996): "OBBTree: A Hierarchical Structure for Rapid Interference Detection." The contents of the SIGGRAPH article are herein incorporated by reference.

The algorithm is centered around a recursive subdivision of the space occupied by an object, which is organized in a binary-tree like fashion. Triangles are used to represent the teeth in the DDS. Each node of the tree is referred to as an oriented bounding box (OBB) and contains a subset of triangles appearing in the node's parent. The children of a parent node contain between them all of the triangle data stored in the parent node.

The bounding box of a node is oriented so it tightly fits around all of the triangles in that node. Leaf nodes in the tree ideally contain a single triangle, but can possibly contain more than one triangle. Detecting collisions between two objects involves determining if the OBB trees of the objects intersect. FIG. 9A sets forth a flow chart depicting a simplified version of a recursive collision test to check if a node "N1" from a first object intersects with node "N2" of a second object. If the OBBs of the root nodes of the trees overlap, the root's children are checked for overlap. The algorithm proceeds in a recursive fashion until the leaf nodes are reached. At this point, a robust triangle intersection routine is used to determine if the triangles at the leaves are involved in a collision.

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The present invention provides several enhancements to the collision detection algorithm described in the SIGGRAPH article. In one embodiment, the present invention provides a unique method of building OBB trees in a lazy fashion to save memory and time. This approach stems from the observation that there are parts of the model which will never be involved in a collision, and consequently the OBB tree for such parts of the model need not be computed. The OBB trees are expanded by splitting the internal nodes of the tree as necessary during the recursive collision determination algorithm, as depicted in FIG. 9B.

In another embodiment of the present invention, the triangles in the model which are not required for collision data may also be specifically excluded from consideration when building an OBB tree. As depicted in FIG. 9C, additional information is provided to the collision algorithm to specify objects in motion. Motion may be viewed at two levels. Objects may be conceptualized as "moving" in a global sense, or they may be conceptualized as "moving" relative to other objects. The additional information improves the time taken for the collision detection by avoiding recompilation of collision information between objects which are at rest relative to each other since the state of the collision between such objects does not change.

The software of the present invention may also incorporate and the user may at any point use a "movie" feature to automatically animate the movement from initial to target states. This is helpful for visualizing overall component movement throughout the treatment process.

Above it was described that the preferred user interface for component identification is a three dimensional interactive GUI. A three-dimensional GUI is also preferred for component manipulation. Such an interface provides the treating professional or user with instant and visual interaction with the digital model components. It is preferred over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular segment. In other words, a GUI adapted for manipulation is preferred over an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots. Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

The software also allows for adding annotations to the datasets which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e. it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and

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teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in FIG. 10. Preferably, fabrication methods will employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 will selectively harden a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 will receive the individual digital data sets and produce one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, it will be preferred to use the prototyping machine to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine may be used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the tradename BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

After production, the plurality of appliances which comprise the system of the present invention are preferably supplied to the treating professional all at one time. The appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

FIG. 11 is a simplified block diagram of a data processing system 300 embodying the present invention. Data processing system 300 typically includes at least one processor 302 which communicates with a number of peripheral devices via bus subsystem 304. These peripheral devices typically include a storage subsystem 306 (memory subsystem 308 and file storage subsystem 314), a set of user interface input and output devices 318, and an interface to outside networks 316, including the public switched telephone network. This interface is shown schematically as "Modems and Network Interface" block 316, and is coupled to corresponding interface devices in other data processing systems via communication network interface 324. Data processing system 300 could be a terminal or a low-end personal computer or a high-end personal computer, workstation or mainframe.

The user interface input devices typically include a keyboard and may further include a pointing device and a scanner. The pointing device may be an indirect pointing device such as a mouse, trackball, touchpad, or graphics tablet, or a direct pointing device such as a touchscreen

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incorporated into the display. Other types of user interface input devices, such as voice recognition systems, are also possible.

User interface output devices typically include a printer and a display subsystem, which includes a display controller and a display device coupled to the controller. The display device may be a cathode ray tube (CRT), a flat-panel device such as a liquid crystal display (LCD), or a projection device. The display subsystem may also provide non-visual display such as audio output.

Storage subsystem 306 maintains the basic programming and data constructs that provide the functionality of the present invention. The software modules discussed above are typically stored in storage subsystem 306. Storage subsystem 306 typically comprises memory subsystem 308 and file storage subsystem 314.

Memory subsystem 308 typically includes a number of memories including a main random access memory (RAM) 310 for storage of instructions and data during program execution and a read only memory (ROM) 312 in which fixed instructions are stored. In the case of Macintosh-compatible personal computers the ROM would include portions of the operating system; in the case of IBM-compatible personal computers, this would include the BIOS (basic input/output system).

File storage subsystem 314 provides persistent (non-volatile) storage for program and data files, and typically includes at least one hard disk drive and at least one floppy disk drive (with associated removable media). There may also be other devices such as a CD-ROM drive and optical drives (all with their associated removable media). Additionally, the system may include drives of the type with removable media cartridges. The removable media cartridges may, for example be hard disk cartridges, such as those marketed by Syquest and others, and flexible disk cartridges, such as those marketed by Iomega. One or more of the drives may be located at a remote location, such as in a server on a local area network or at a site on the Internet's World Wide Web.

In this context, the term "bus subsystem" is used generically so as to include any mechanism for letting the various components and subsystems communicate with each other as intended. With the exception of the input devices and the display, the other components need not be at the same physical location. Thus, for example, portions of the file storage system could be connected via various local-area or wide-area network media, including telephone lines. Similarly, the input devices and display need not be at the same location as the processor, although it is anticipated that the present invention will most often be implemented in the context of PCs and workstations.

Bus subsystem 304 is shown schematically as a single bus, but a typical system has a number of buses such as a local bus and one or more expansion buses (e.g., ADB, SCSI, ISA, EISA, MCA, NuBus, or PCI), as well as serial and parallel ports. Network connections are usually established through a device such as a network adapter on one of these expansion buses or a modem on a serial port. The client computer may be a desktop system or a portable system.

Scanner 320 is responsible for scanning casts of the patient's teeth obtained either from the patient or from an orthodontist and providing the scanned digital data set information to data processing system 300 for further processing. In a distributed environment, scanner 320 may be located at a remote location and communicate scanned digital data set information to data processing system 300 via network interface 324.

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Fabrication machine 322 fabricates dental appliances based on intermediate and final data set information received from data processing system 300. In a distributed environment, fabrication machine 322 may be located at a remote location and receive data set information from data processing system 300 via network interface 324.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:

- a) obtaining a digital data set representing an initial tooth arrangement;
- b) obtaining a repositioned tooth arrangement based on the initial tooth arrangement;
- c) obtaining a series of successive digital data sets representing a series of successive tooth arrangements; and
- d) fabricating a predetermined series of dental incremental position adjustment appliances based on the series of successive digital data sets, wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth, and said appliances correspond to the series of successive tooth arrangements progressing from the initial to the repositioned tooth arrangement.

2. A method as in claim 1, wherein the step of obtaining an initial digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.

3. A method as in claim 1, wherein the step of obtaining a digital data set representing a repositioned tooth arrangement comprises:

- defining boundaries about at least some of the individual teeth; and
- moving at least some of the tooth boundaries relative to the other teeth in an image based on the digital data set to produce the repositioned data set.

4. A method as in claim 1, wherein the step of obtaining space of successive digital data sets comprises determining positional differences between the initial data set and the repositioned data set and interpolating said differences.

5. A method as in claim 4, wherein the interpolating step comprises linear interpolation.

6. A method as in claim 4, wherein the interpolating step comprises non-linear interpolation.

7. A method as in claim 4, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.

8. A method as in claim 1, wherein the fabricating step comprises:

- controlling a fabrication machine based on the series of digital data sets to produce a series of positive models of the series of tooth arrangements; and
- producing the dental appliances as a negative of the positive models.

9. A method as in claim 8 wherein the controlling step comprises:

- providing a volume of non-hardened polymeric resin; and
- selectively hardening the resin to produce the positive mold.

10. A method as in claim 9, wherein the producing step comprises molding the appliances over the positive models.

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11. A method as in claim 1, wherein the fabricating step comprises:
 controlling a fabrication machine to selective harden a portion of a non-hardened polymeric resin to directly produce the appliances.
12. A method for making a system to reposition teeth, comprising:
 a) obtaining an initial digital data set representing an initial tooth arrangement;
 b) obtaining a series of successive digital data sets based on the initial digital data set, wherein the series of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to a repositioned tooth arrangement; and
 c) fabricating a predetermined series of dental incremental position adjustment appliances for incrementally repositioning teeth based on the series of successive digital data sets, and wherein said appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth.
13. A method as in claim 12, wherein the step of obtaining a initial digital data set representing an initial tooth arrangement comprises scanning a three-dimensional model of a patient's teeth.
14. A method as in claim 12, wherein the step of obtaining a series of successive digital data sets comprises determining positions differences between the initial data set and a repositioned data set represent the repositioned tooth arrangement and interpolating said differences.

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15. A method as in claim 14, wherein the interpolating step comprises linear interpolation.
16. A method as in claim 14 wherein the interpolating step comprises non-linear interpolation.
17. A method as in claim 14, further comprising defining one or more key frames between the initial tooth arrangement and final tooth arrangement and interpolating between the key frames.
18. A method as in claim 12, wherein the fabricating step comprises:
 controlling a fabrication machine based on the series of digital data sets to produce a series positive models of the series of tooth arrangements; and
 producing the dental appliances as a negative of the positive models.
19. A method as in claim 18 wherein the controlling step comprises:
 providing a volume of non-hardened polymeric resin; and
 scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive models.
20. A method as in claim 18, wherein the producing step comprises molding the appliances over the positive models.
21. A method as in claim 12, wherein the fabricating step comprises:
 controlling a fabrication machine to selective harden a portion of a non-hardened polymeric resin to directly produce the appliances.

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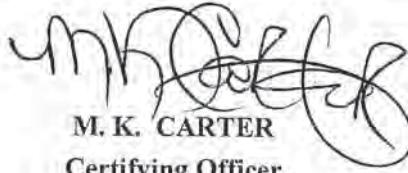
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(12) **United States Patent**
Chishti et al.

(10) Patent No.: US 7,134,874 B2
(45) Date of Patent: Nov. 14, 2006

(54) COMPUTER AUTOMATED DEVELOPMENT OF AN ORTHODONTIC TREATMENT PLAN AND APPLIANCE

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(51) Int. Cl.
A61C 3/00 (2006.01)

(52) U.S. Cl. 433/24; 433/6

(58) Field of Classification Search 433/24,
433/6, 213
See application file for complete search history.

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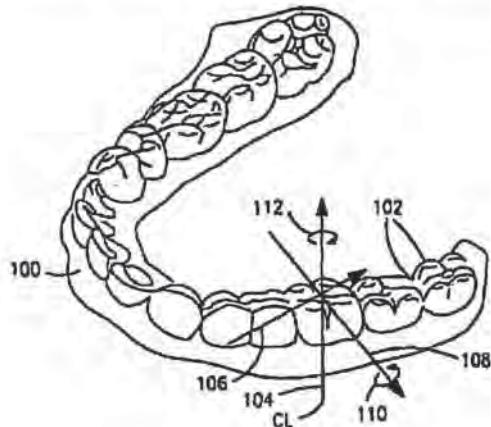
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(57) ABSTRACT

A computer is used to create a plan for repositioning an orthodontic patient's teeth. The computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer then uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.

99 Claims, 28 Drawing Sheets



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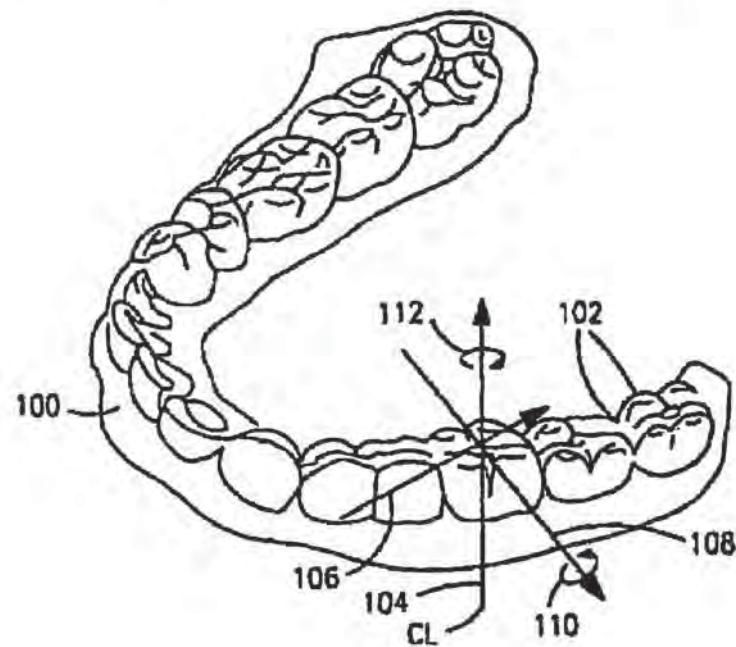


FIG. IA

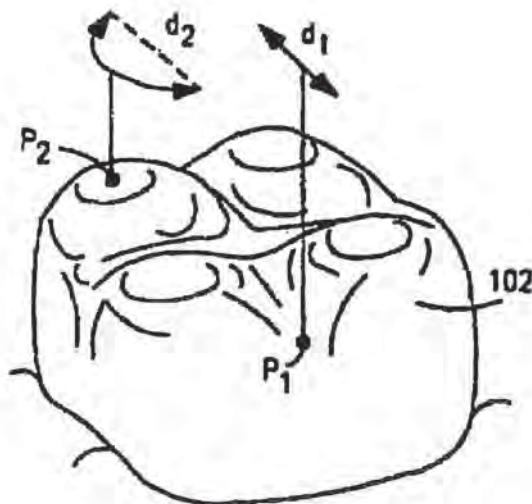


FIG. IB

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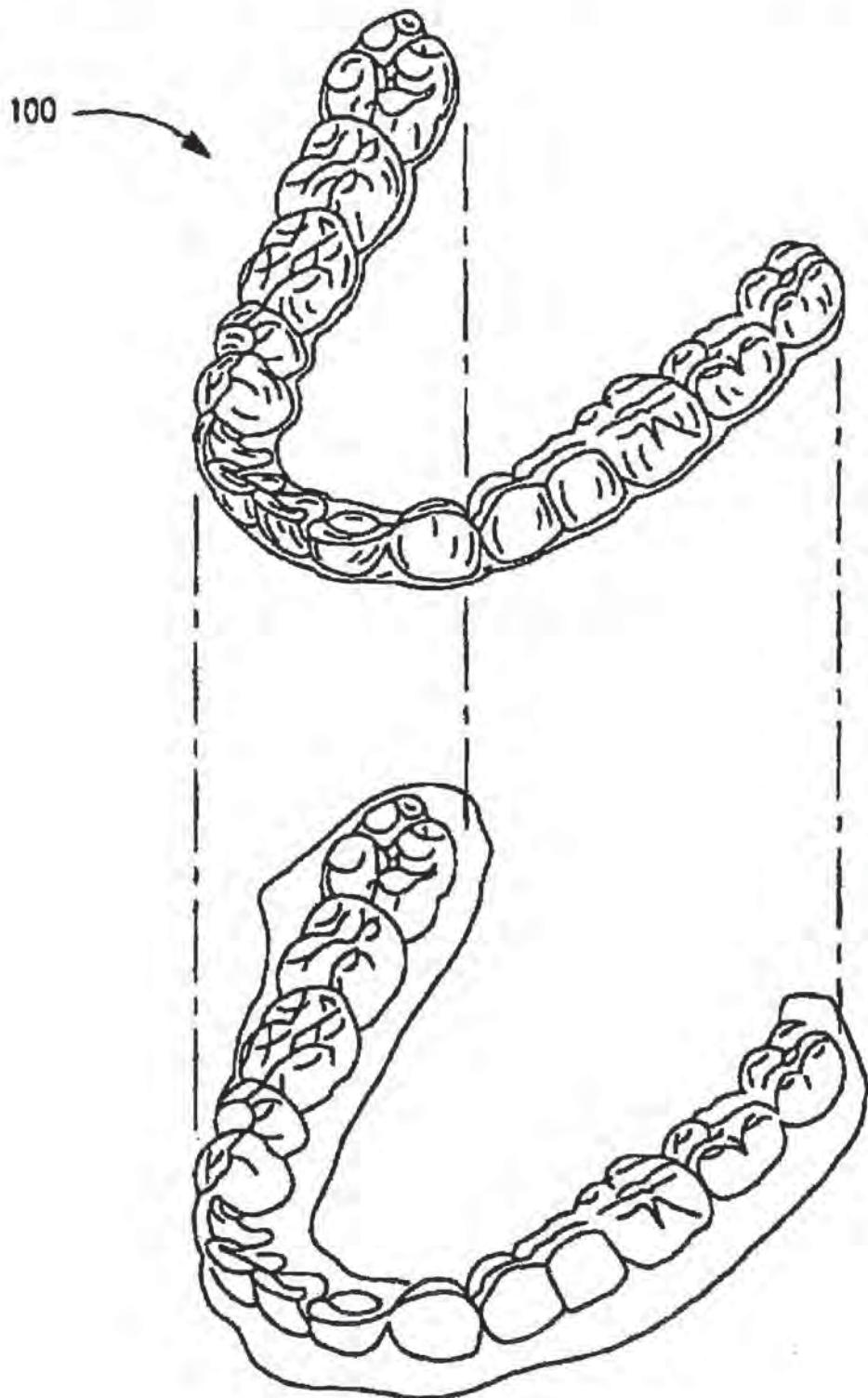


FIG. IC

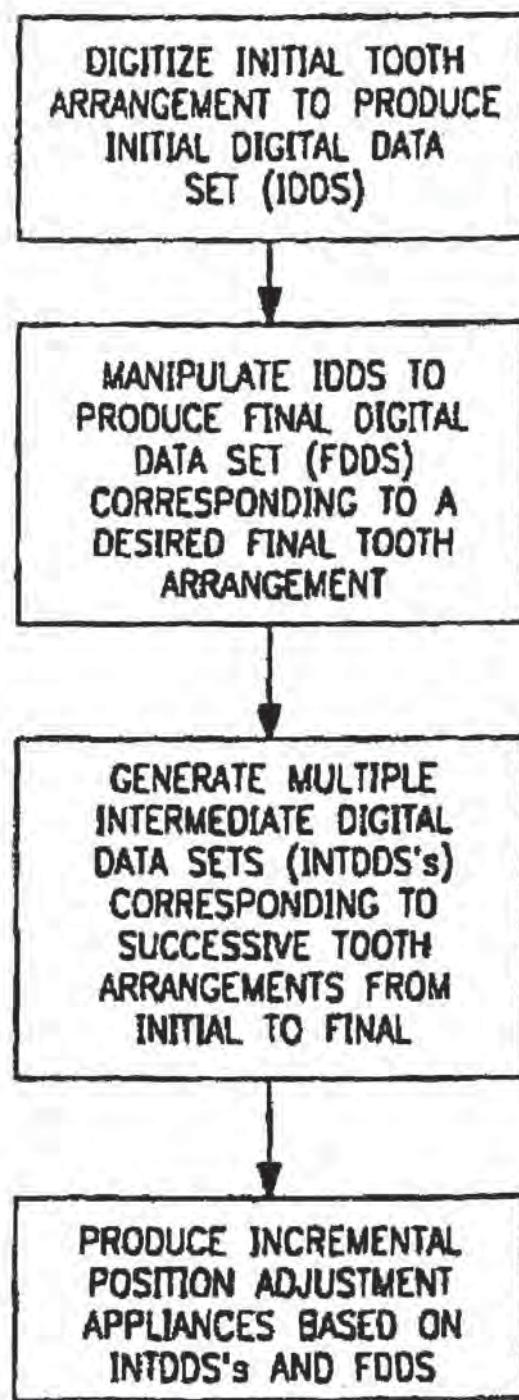
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CROSS-REFERENCE
FIG. 3

CROSS-REFERENCE
FIG. 6

FIG. 2

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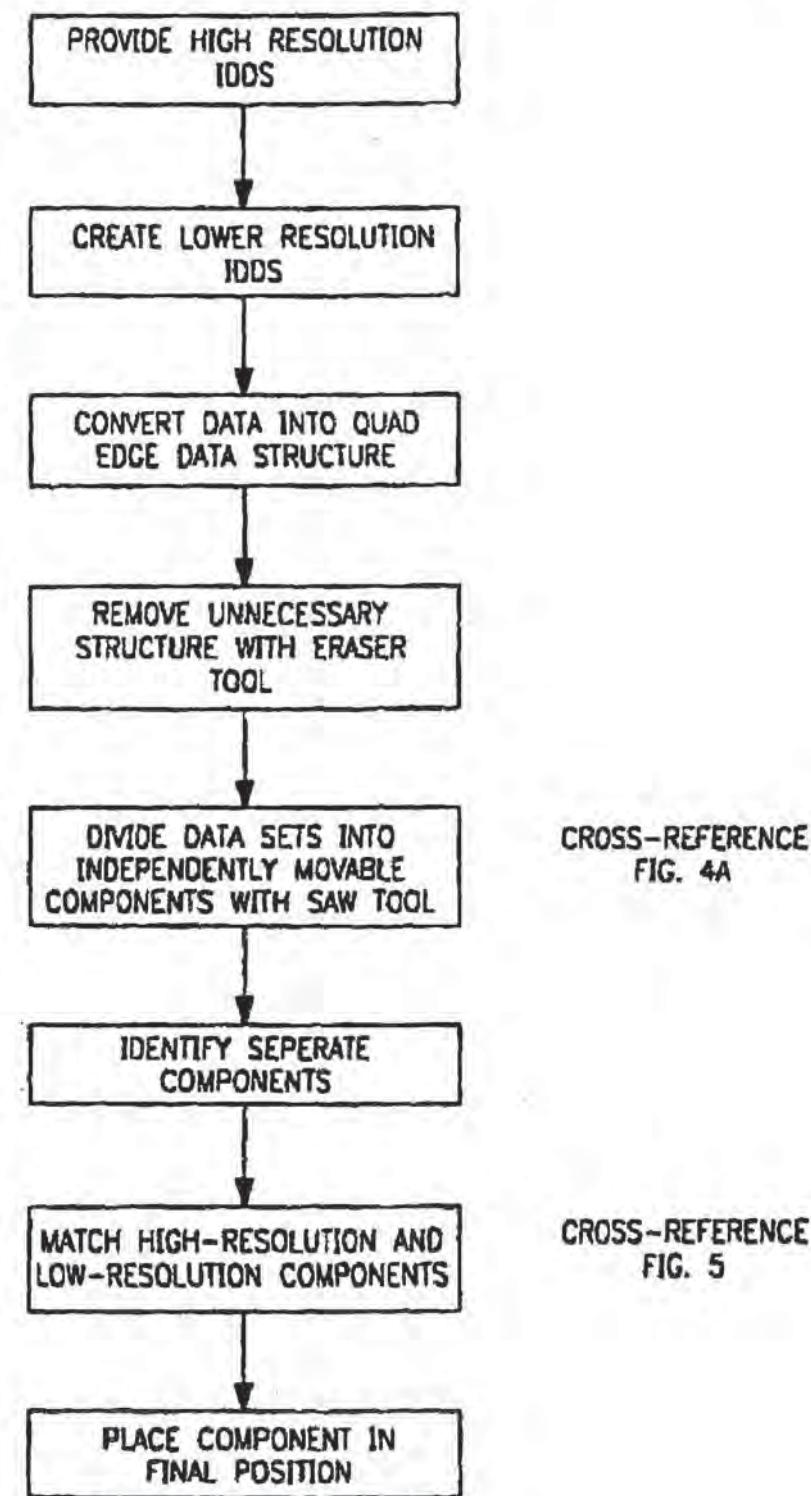


FIG. 3

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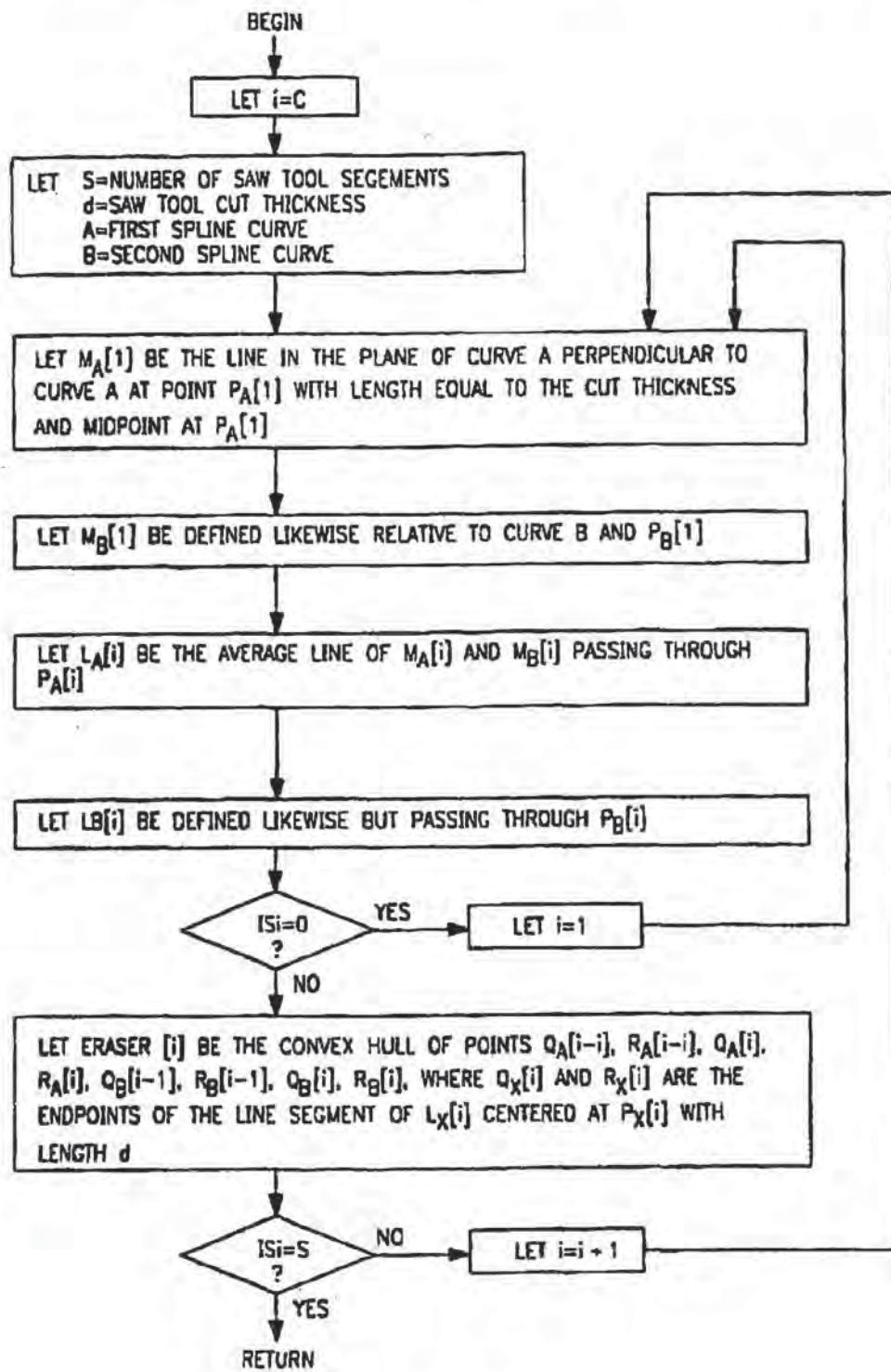


FIG. 4A

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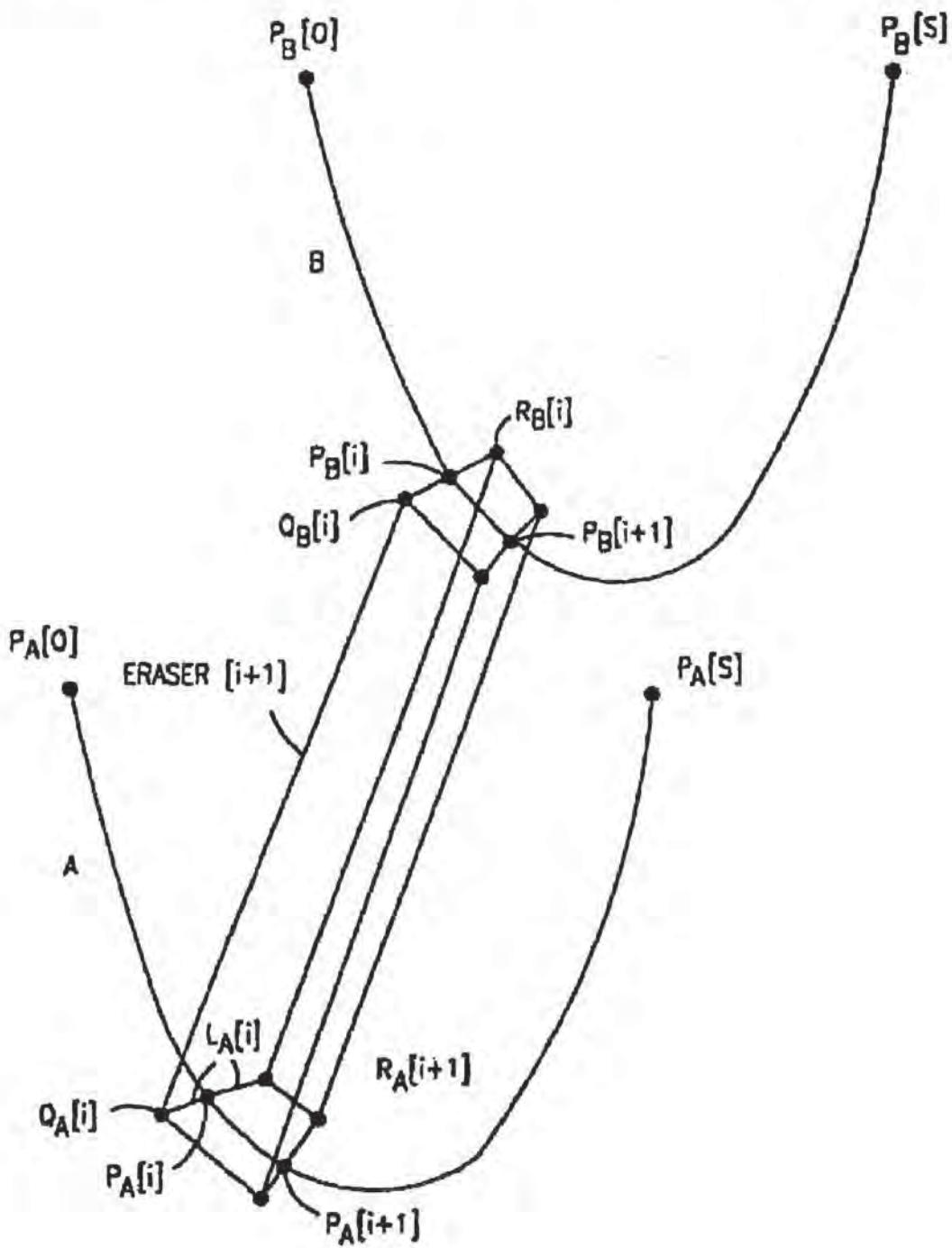


FIG. 4B

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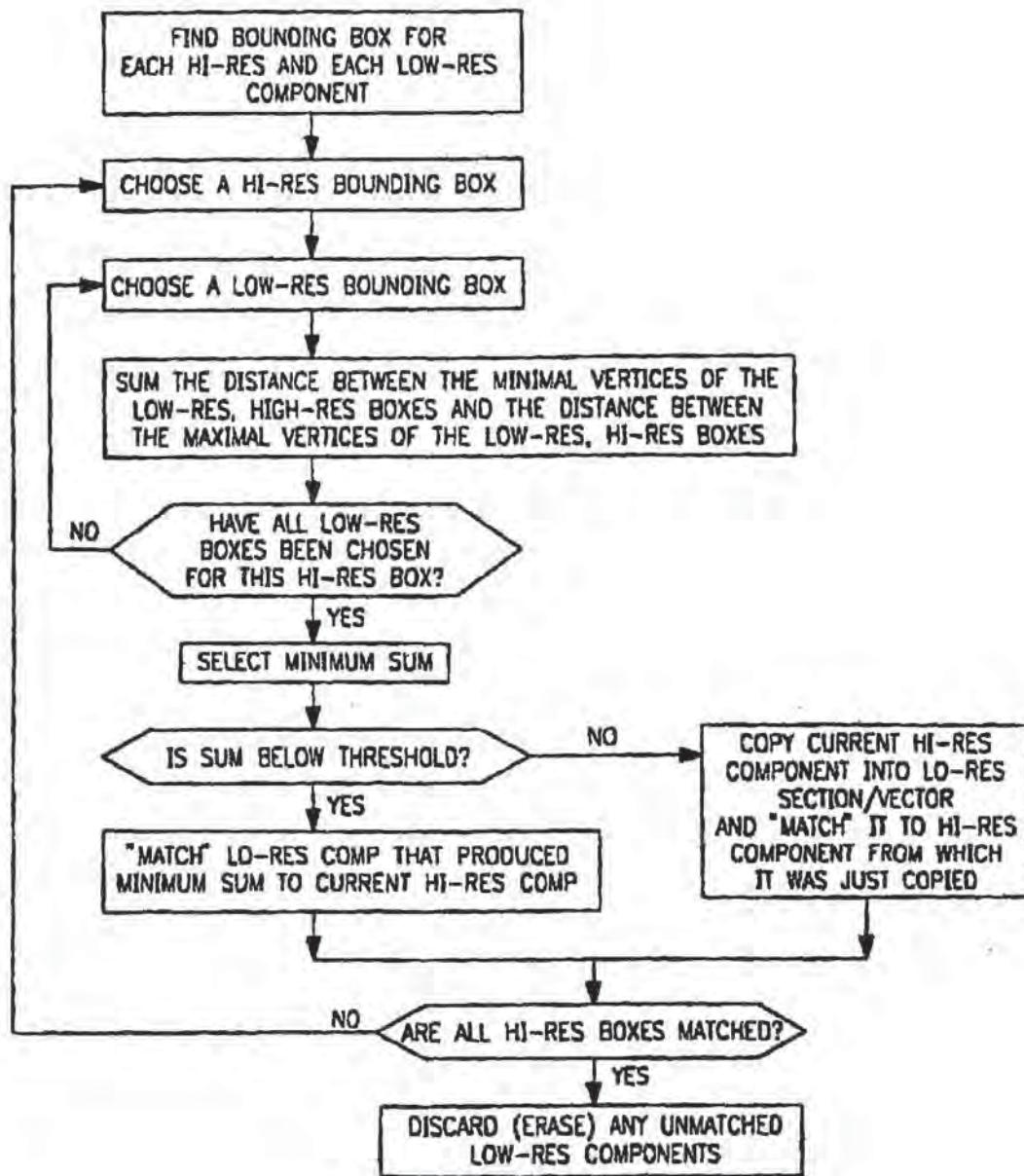


FIG. 5

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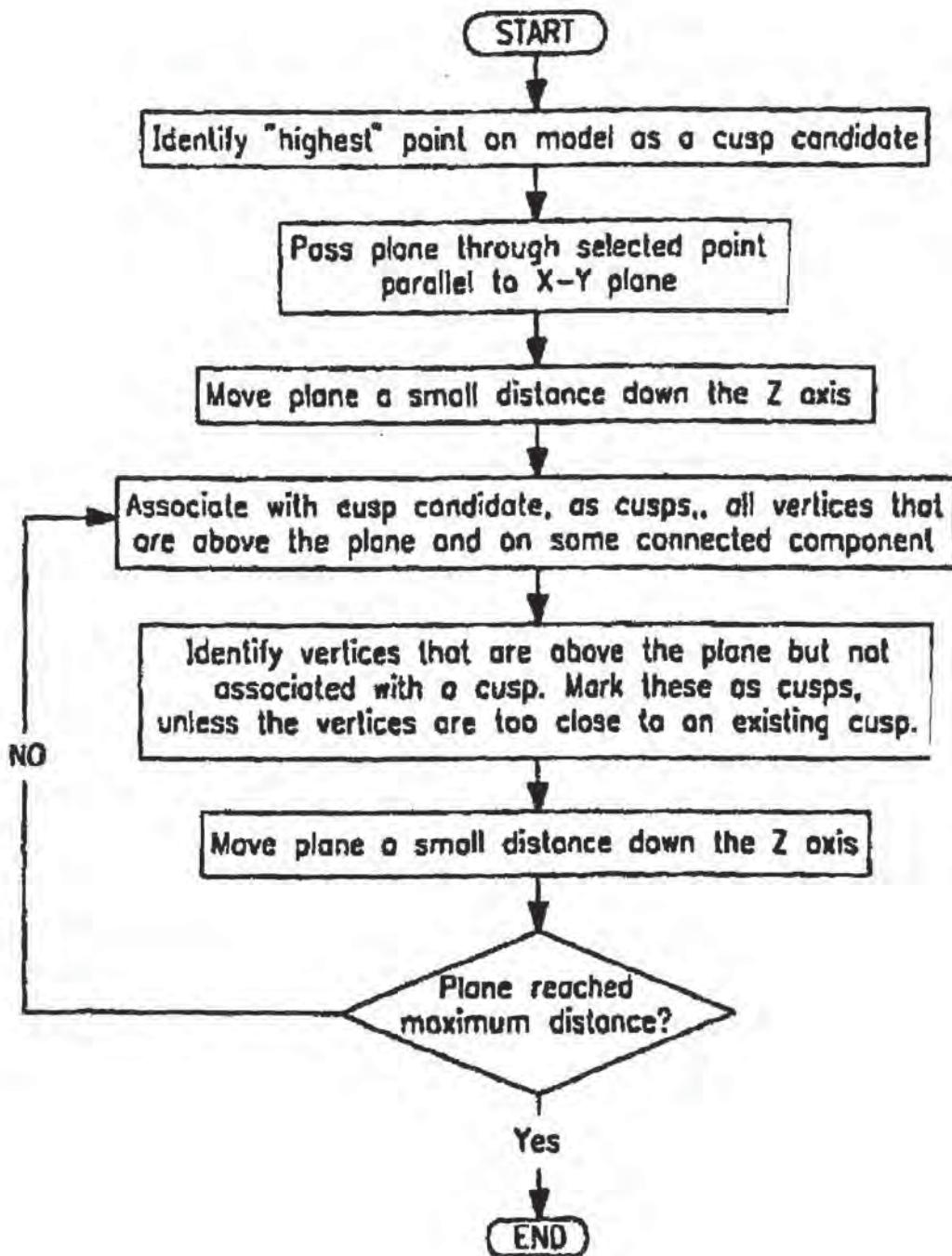


FIG. 6A

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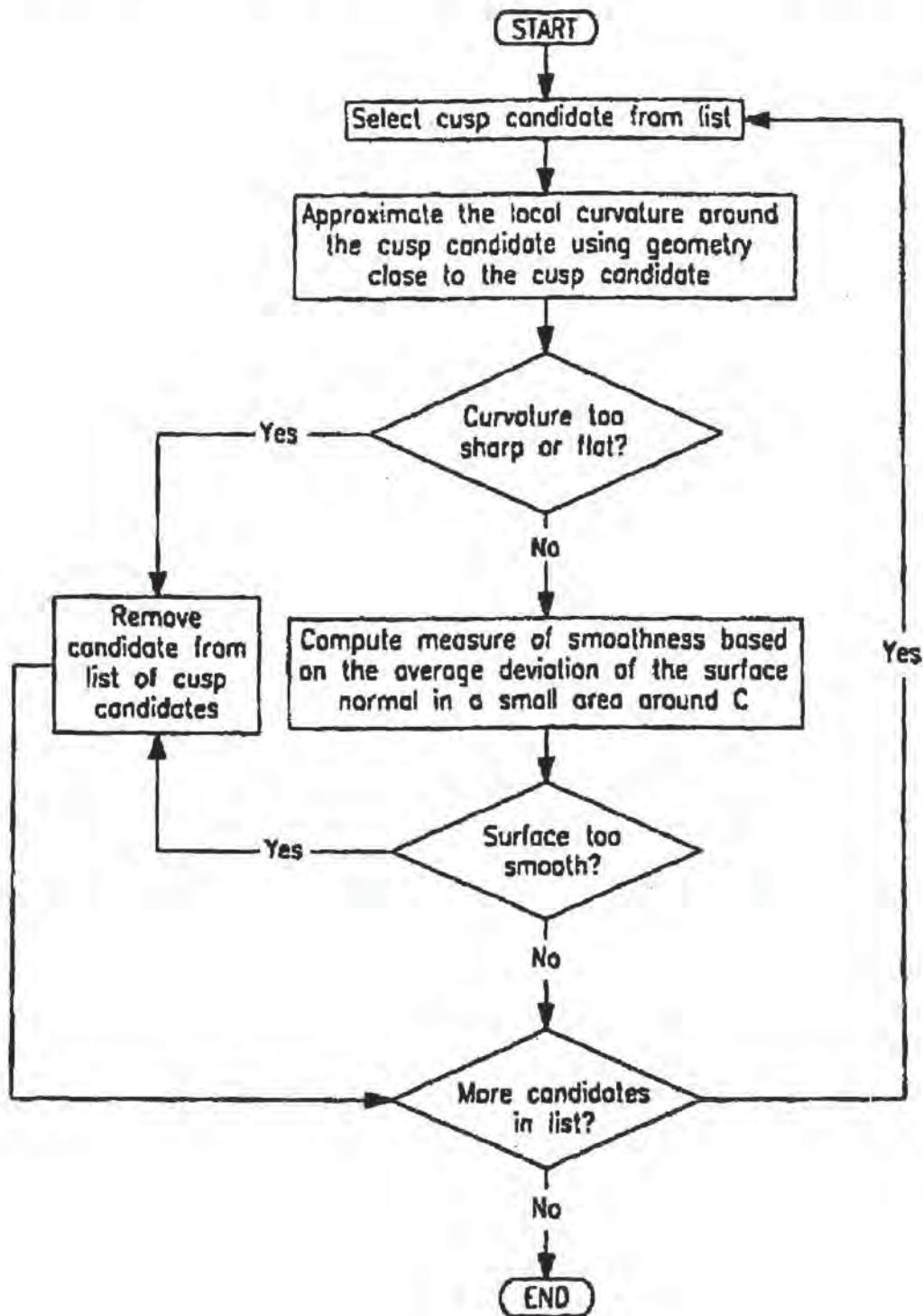


FIG. 6B

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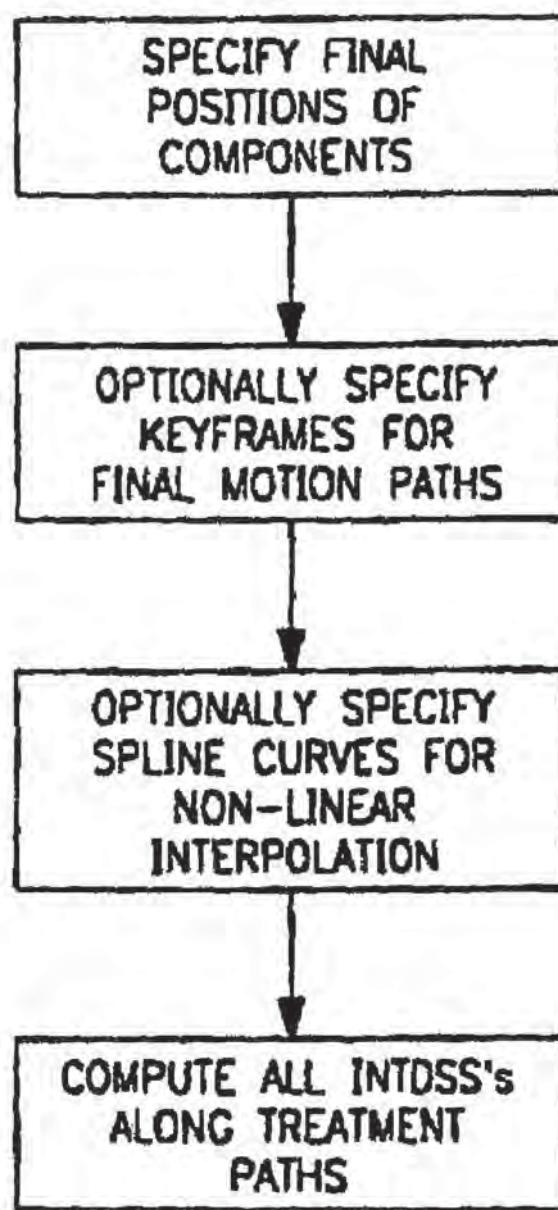


FIG. 7

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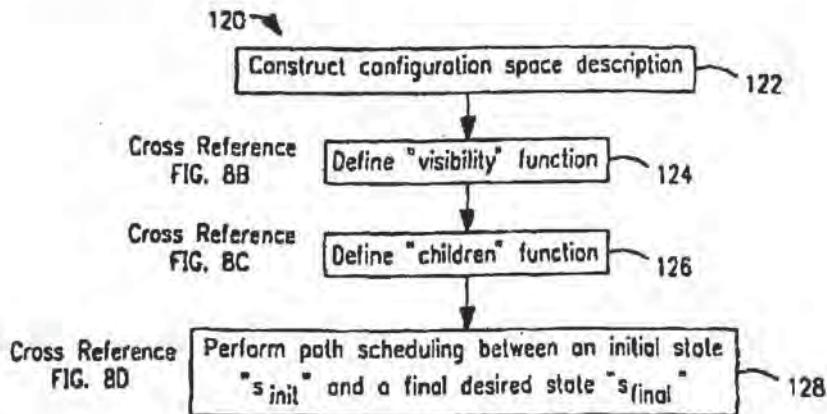


FIG. 8A

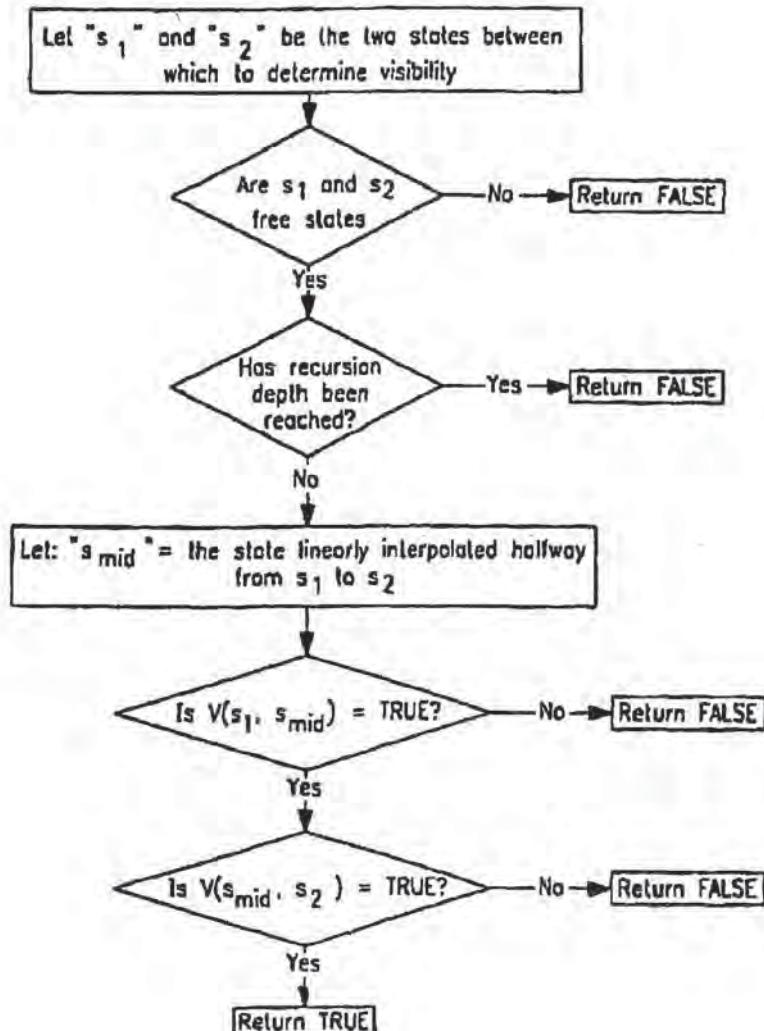


FIG. 8B

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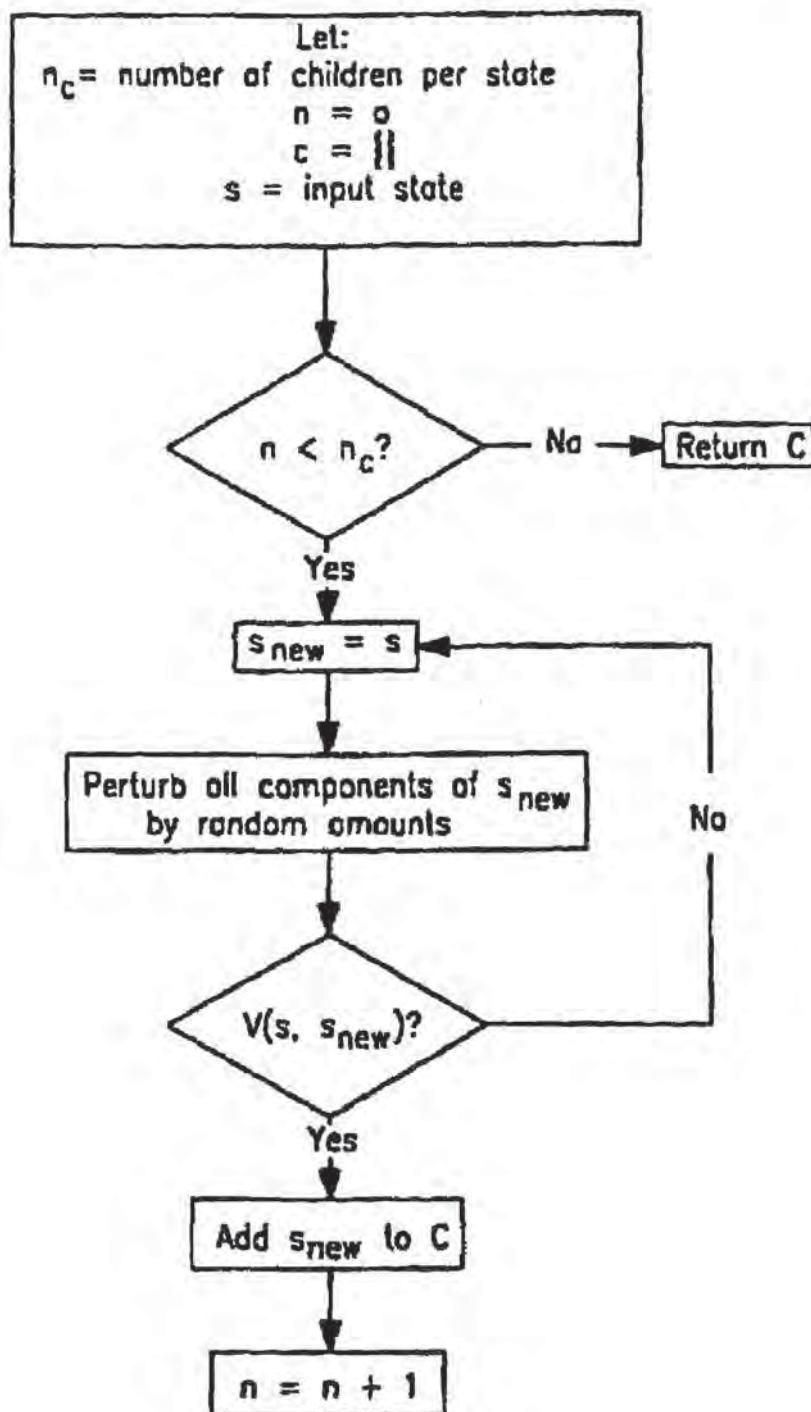


FIG. 8C

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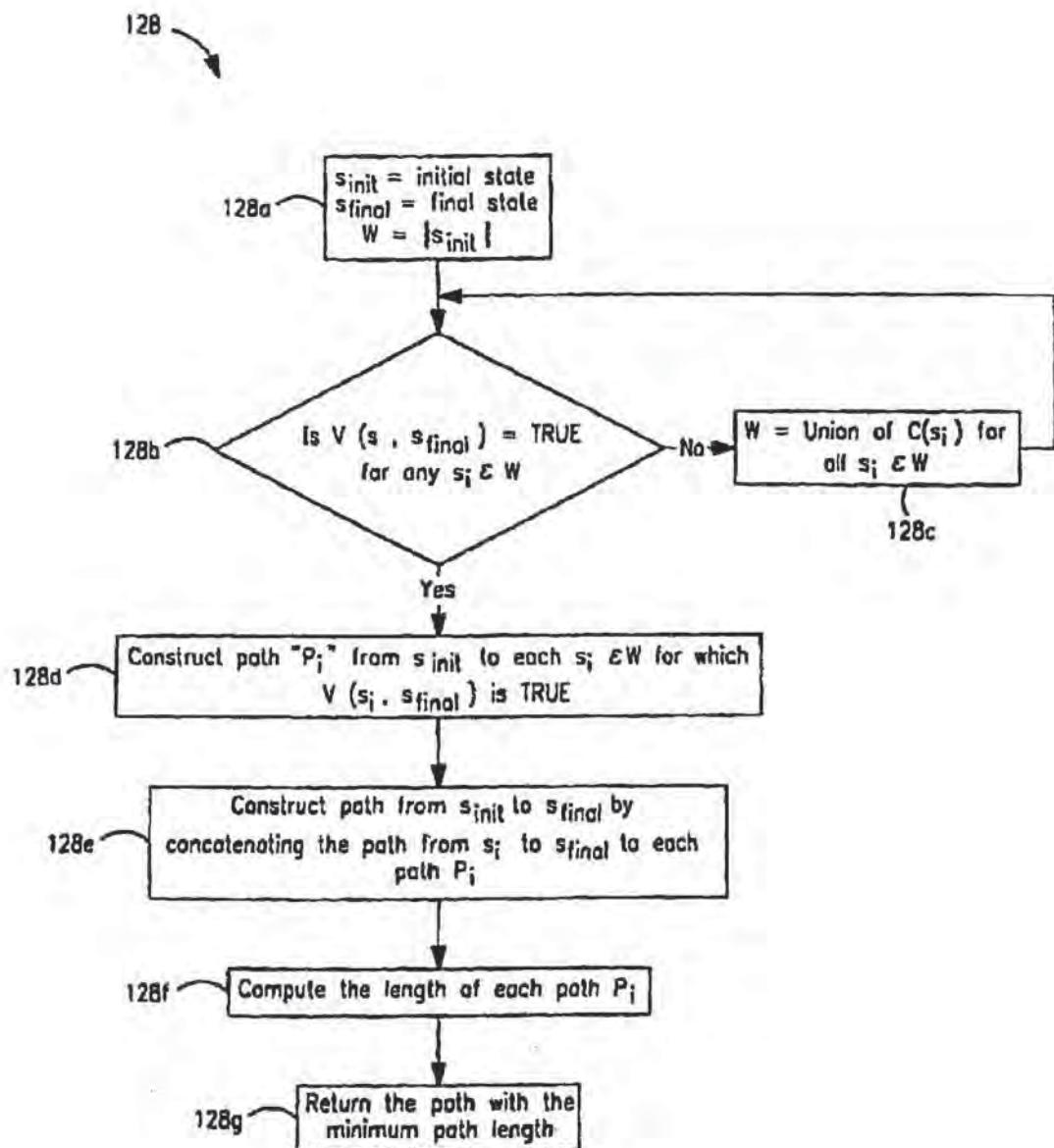


FIG. 8D

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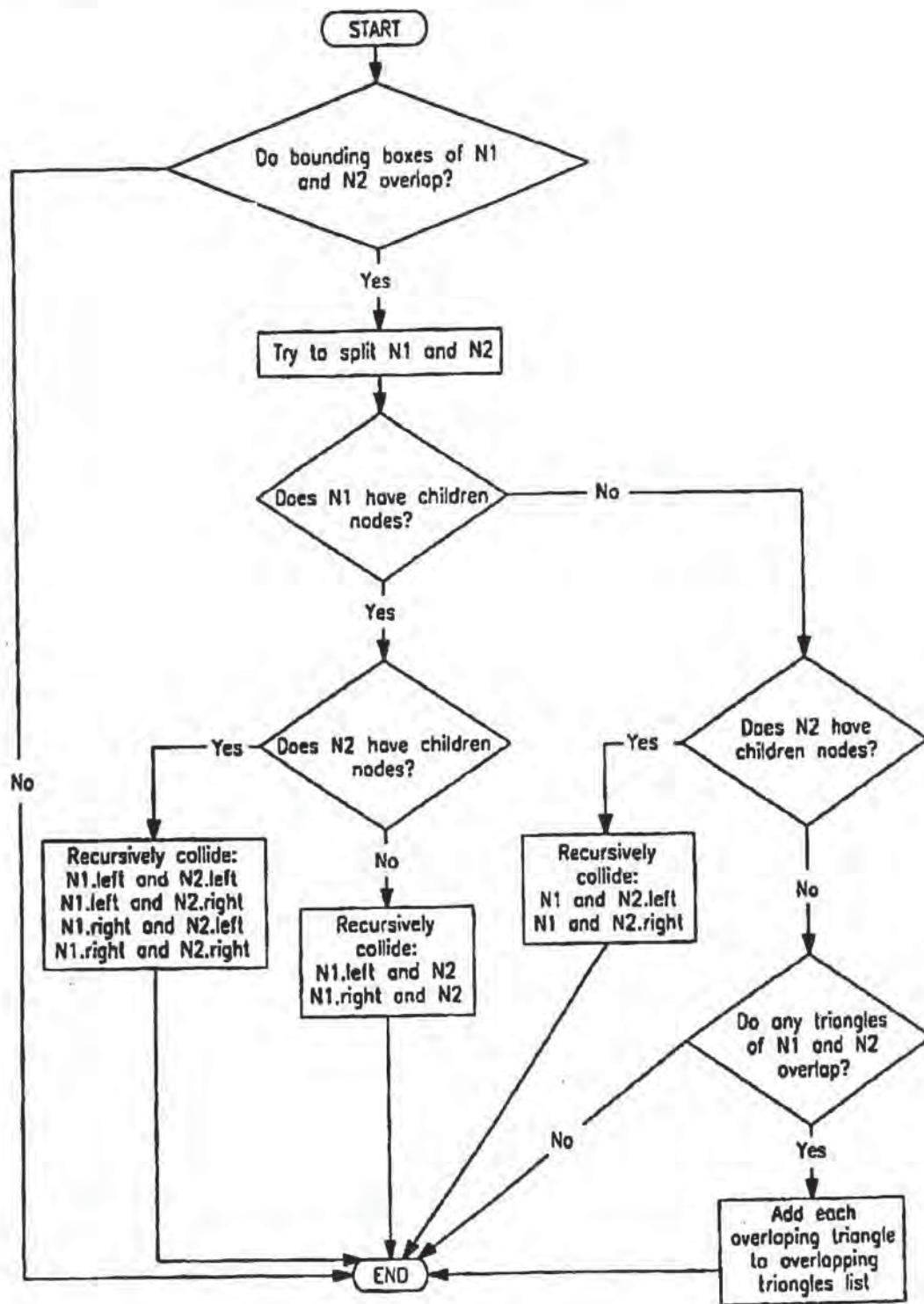


FIG. 9A

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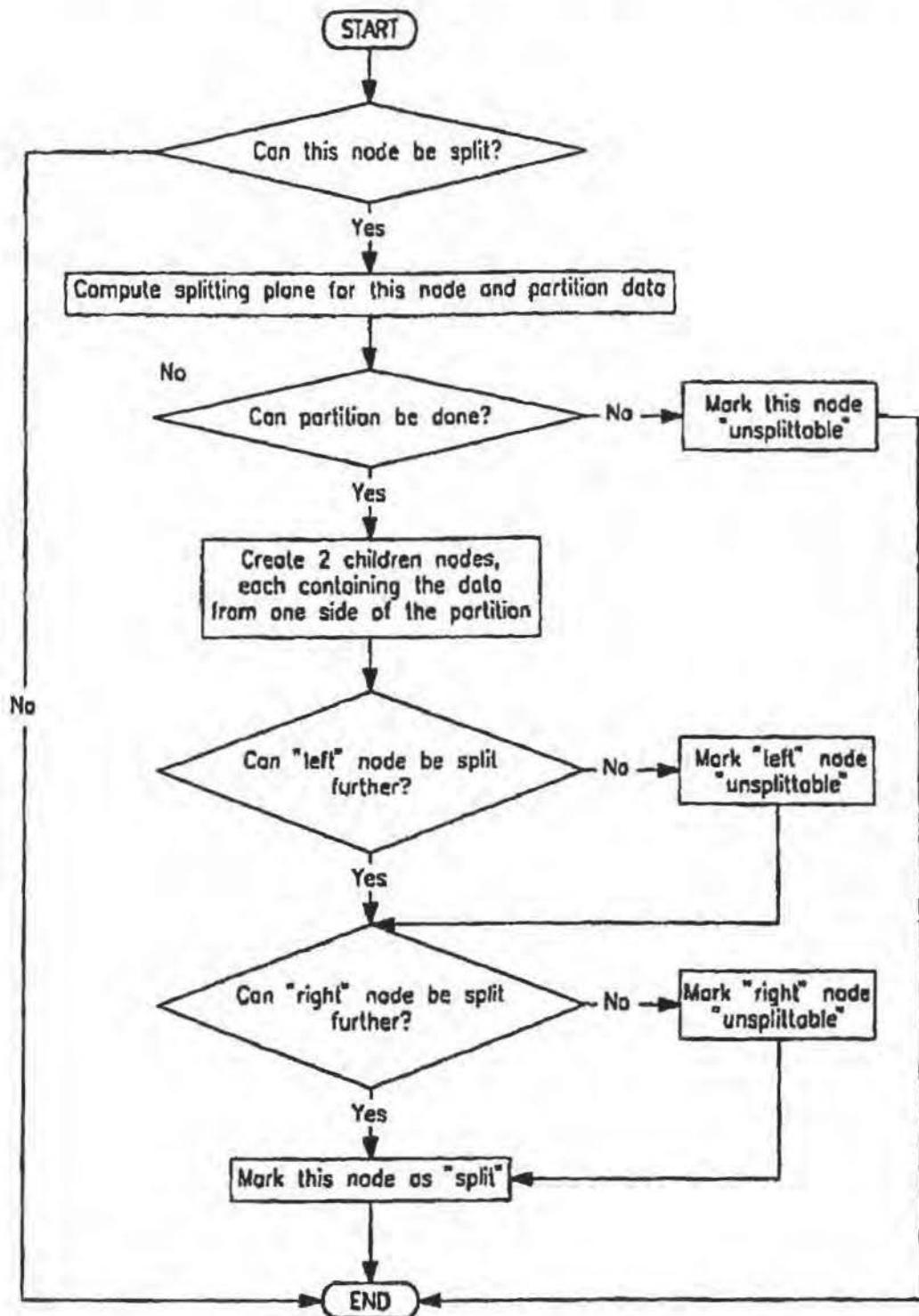


FIG. 9B

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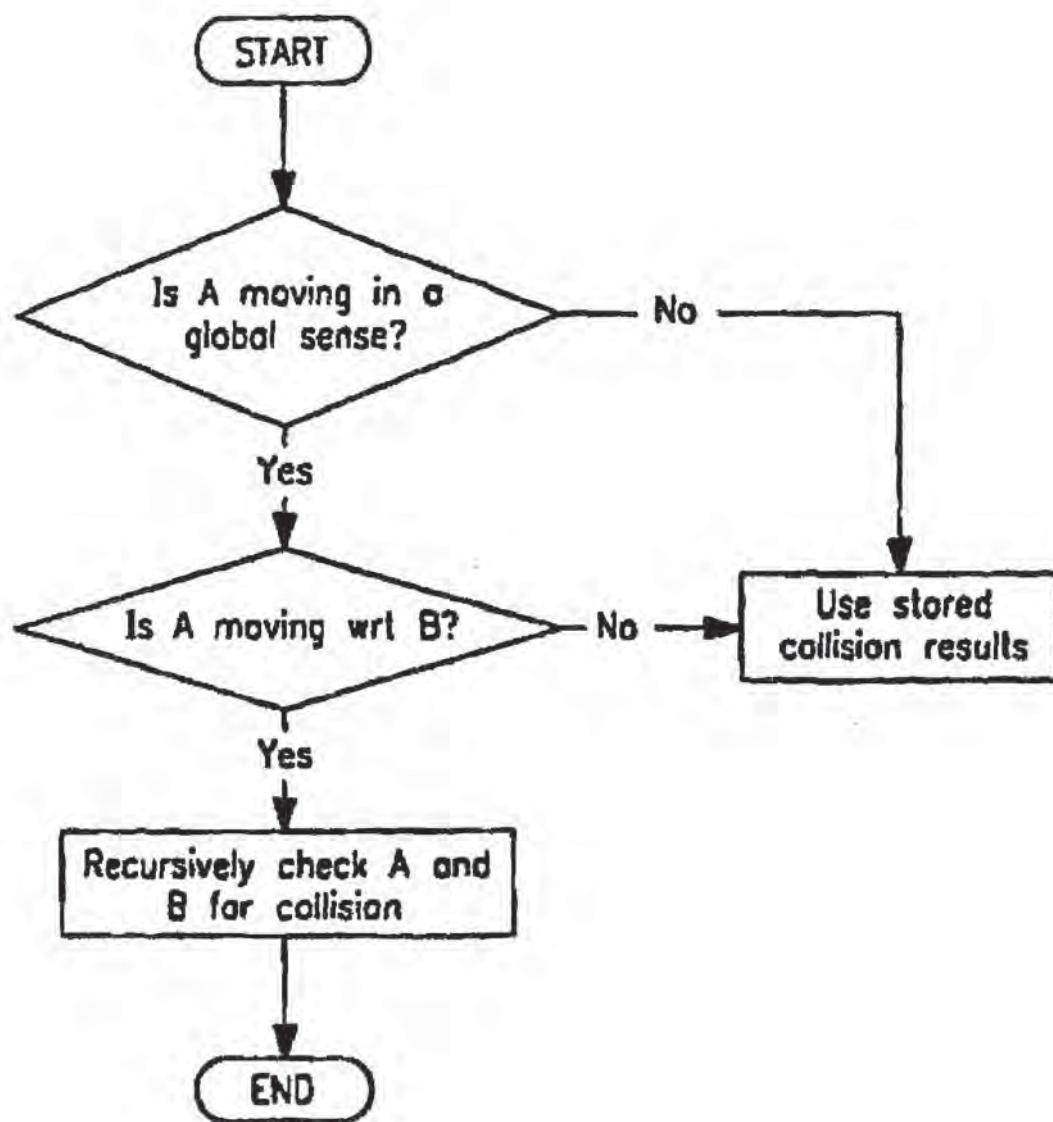


FIG. 9C

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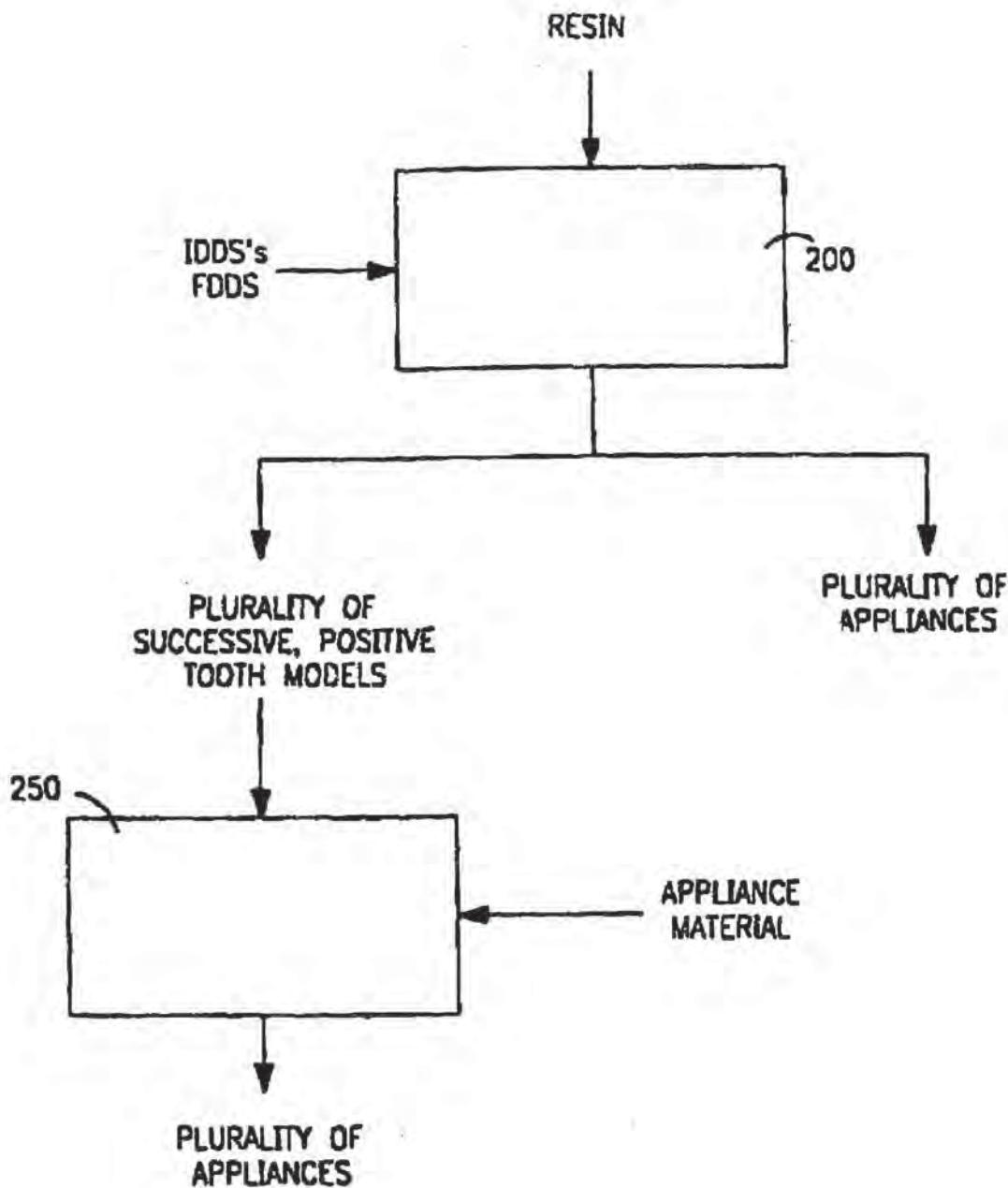


FIG. 10

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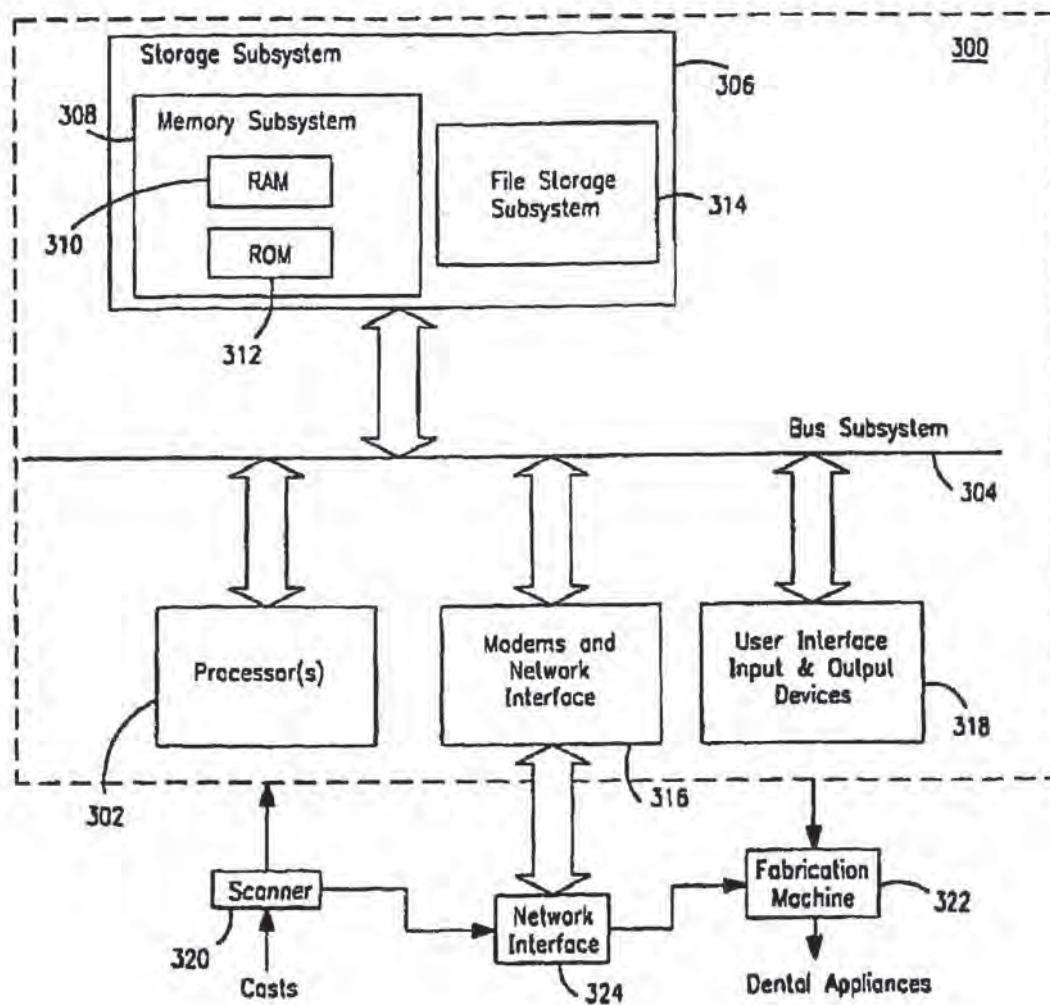


FIG. 11

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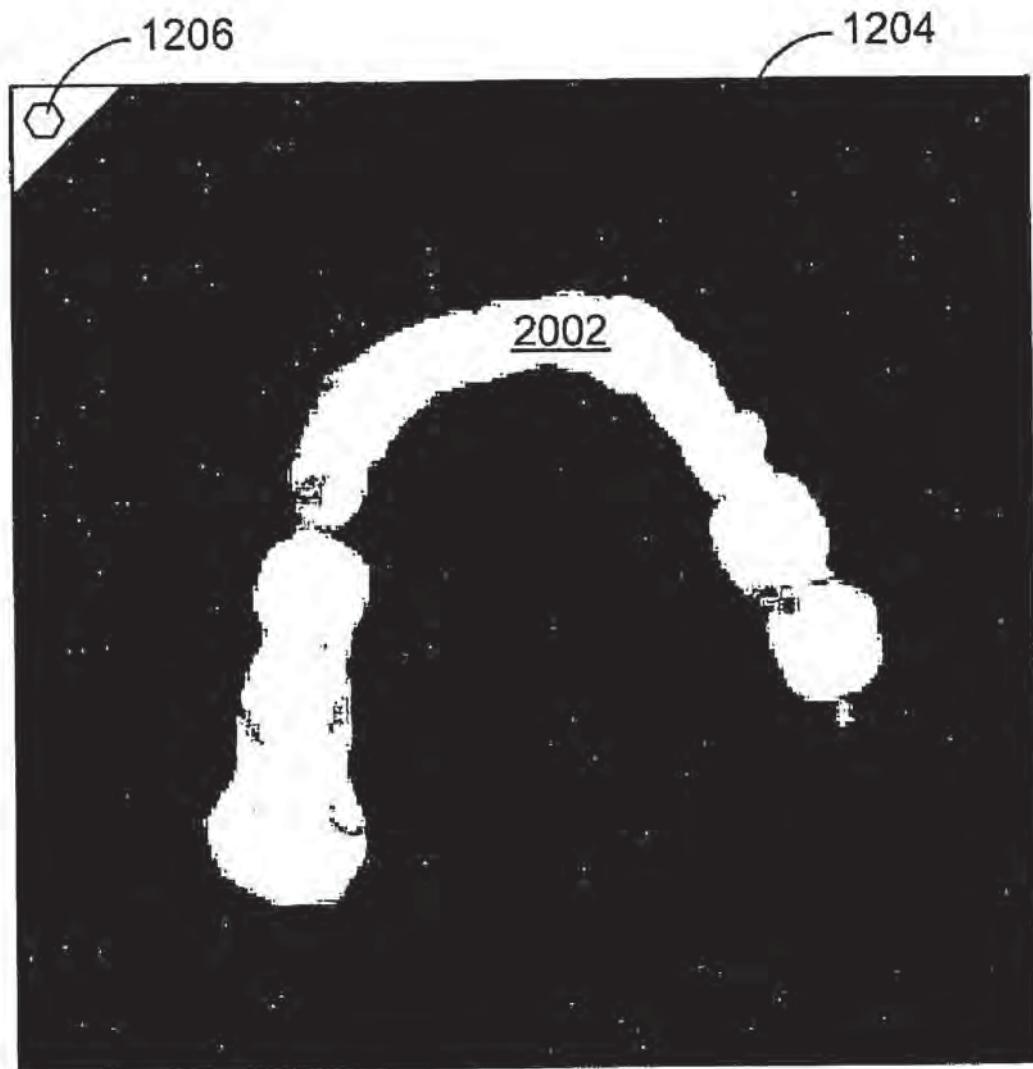


FIG. 12

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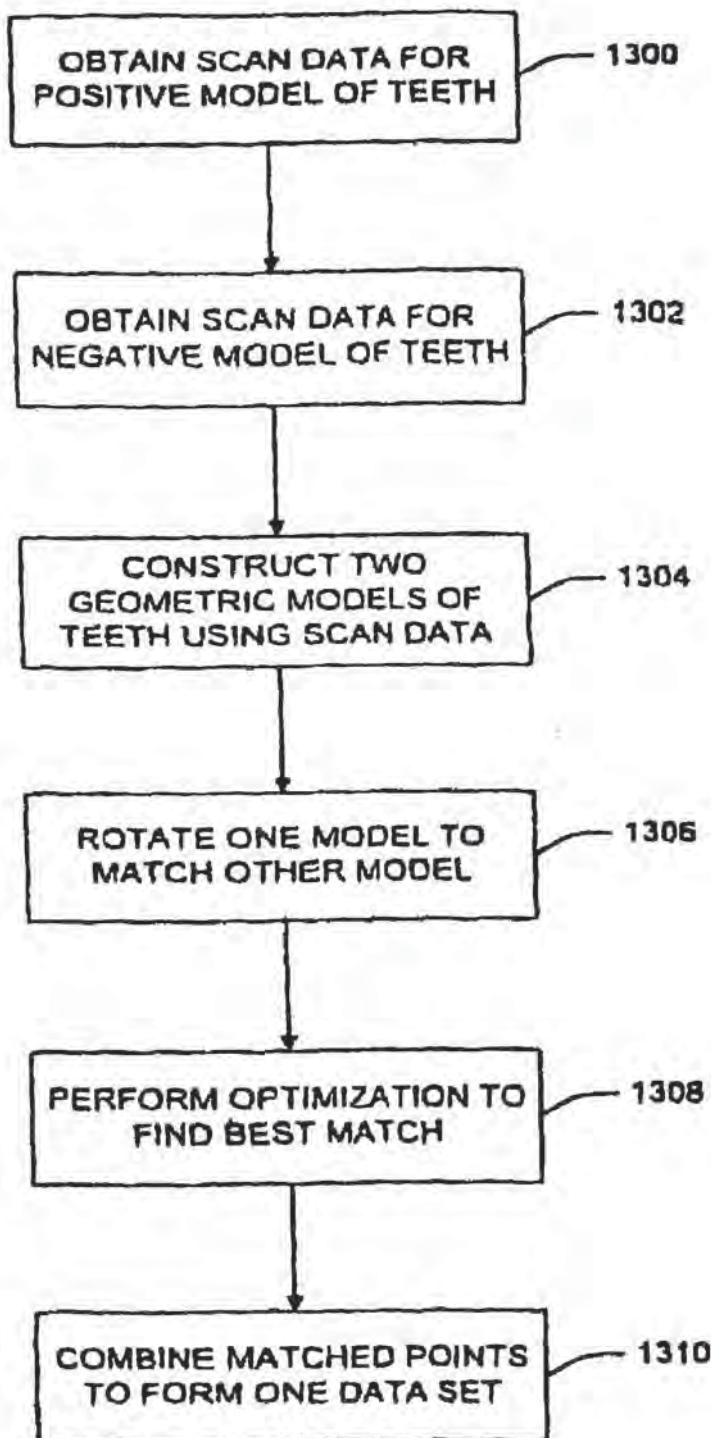


FIG. 13

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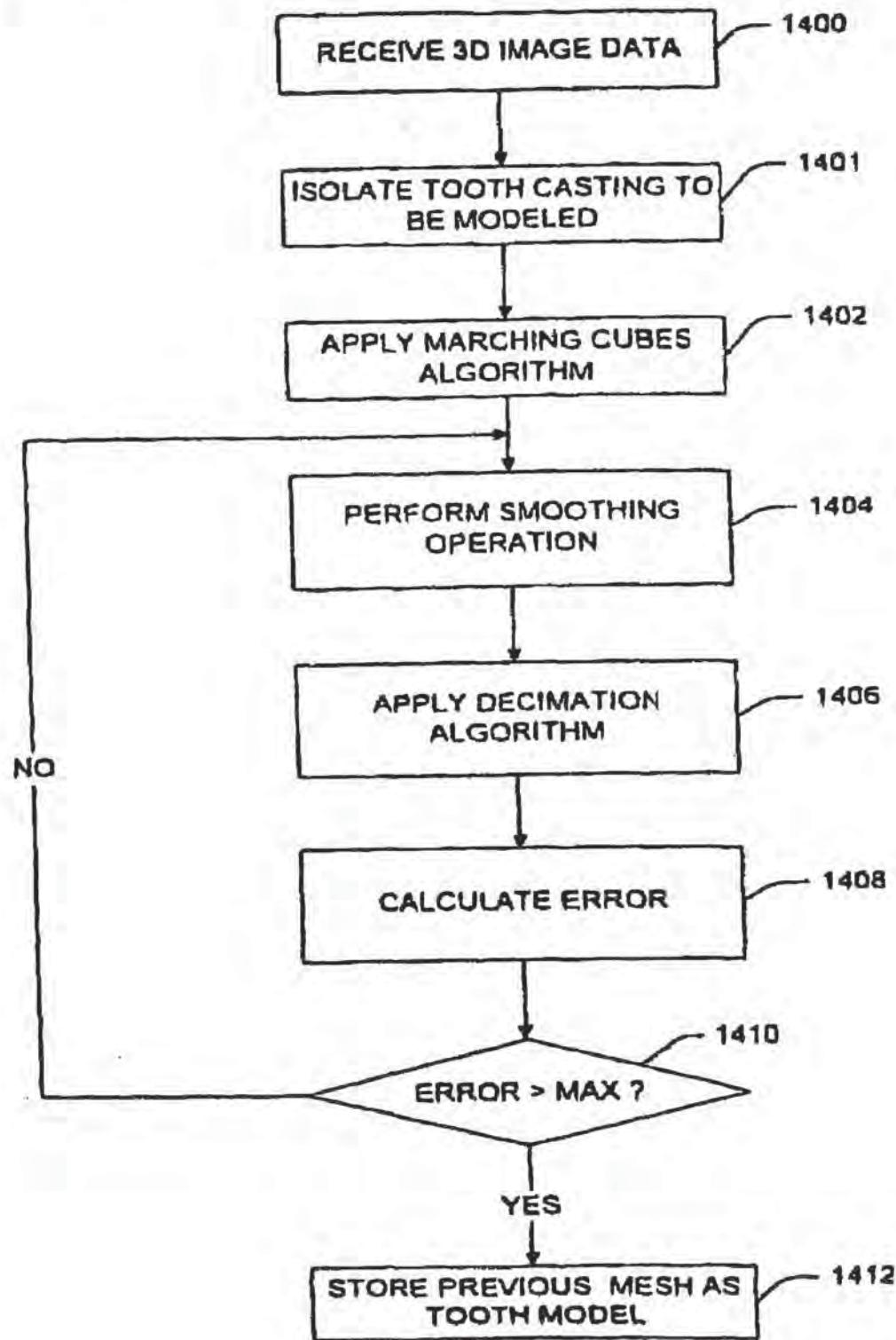


FIG. 14

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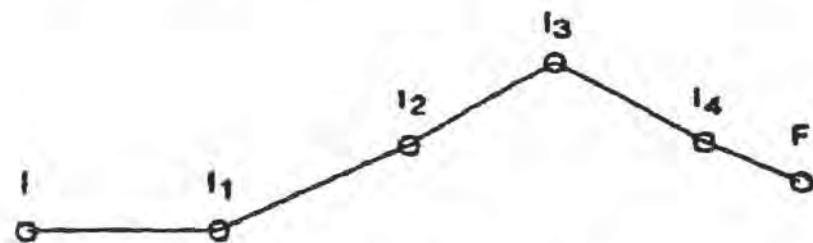


FIG. 15A

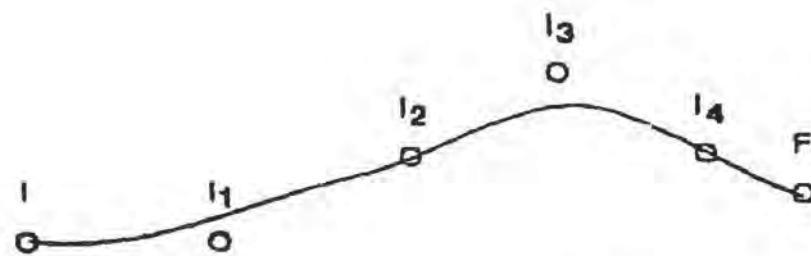


FIG. 15B

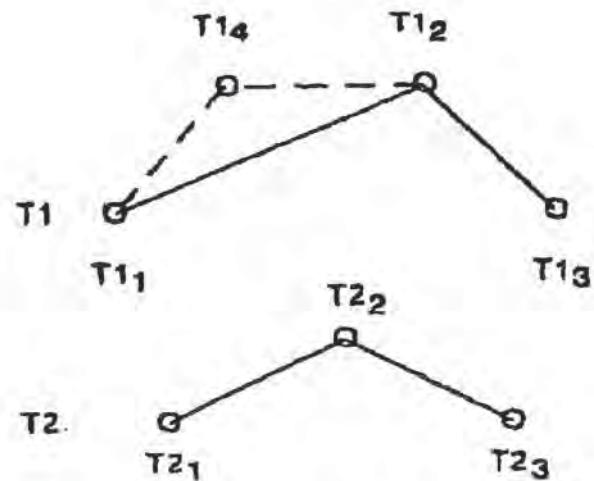


FIG. 15C

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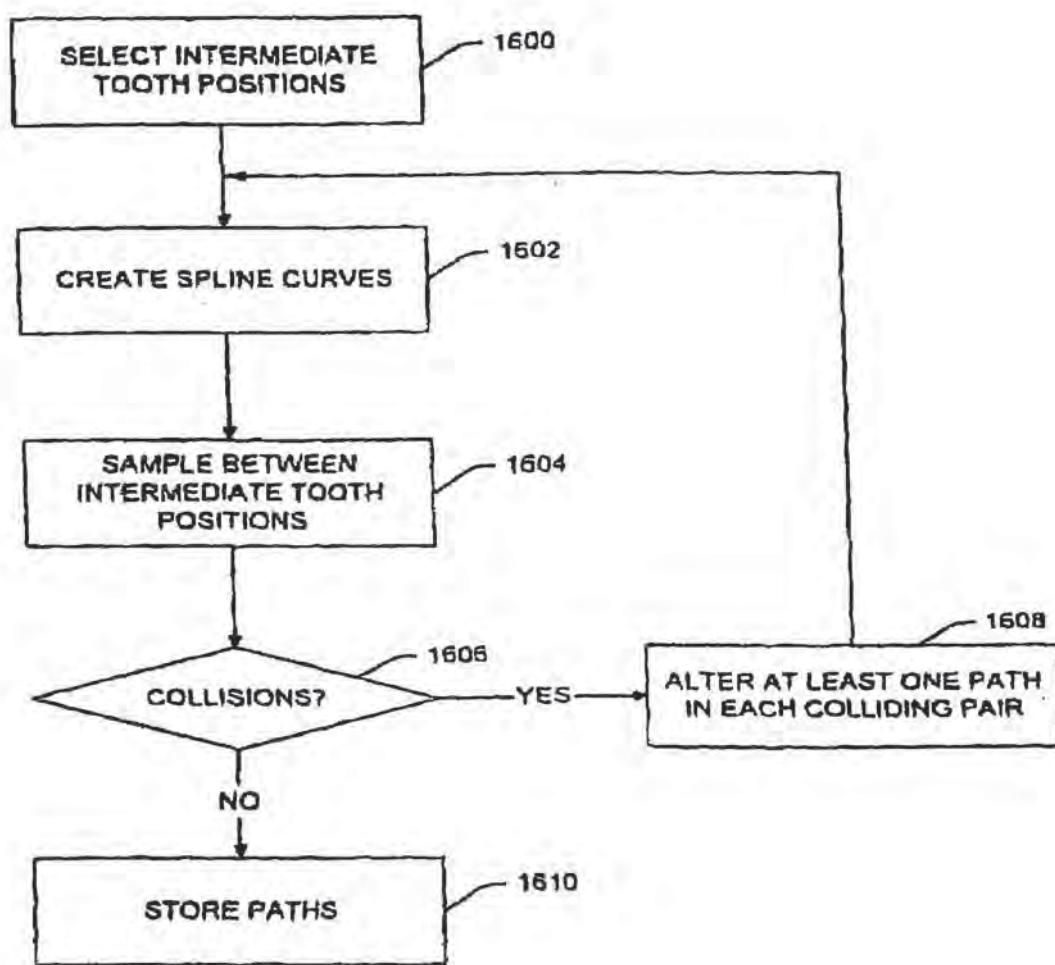


FIG. 16

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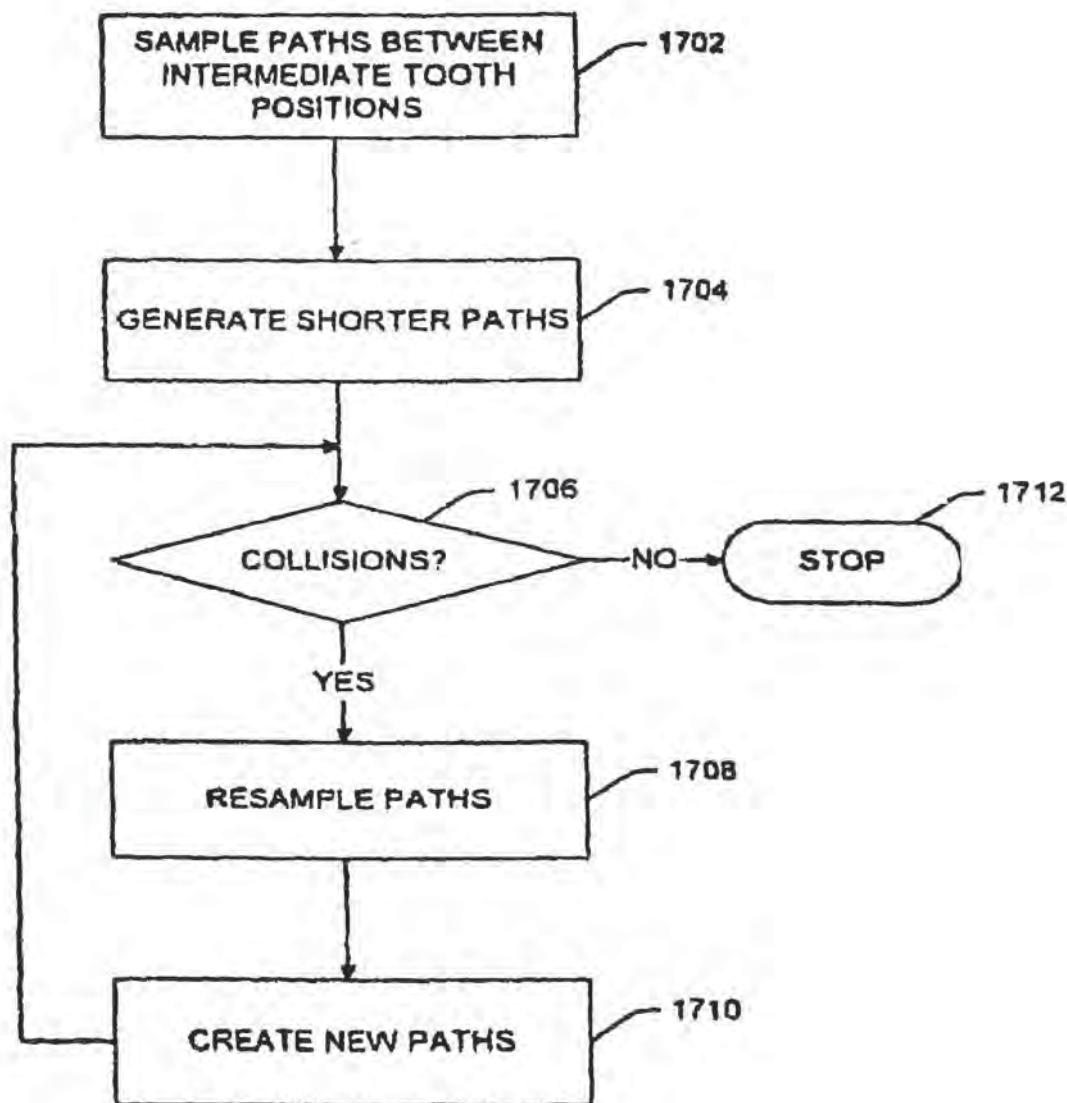


FIG. 17

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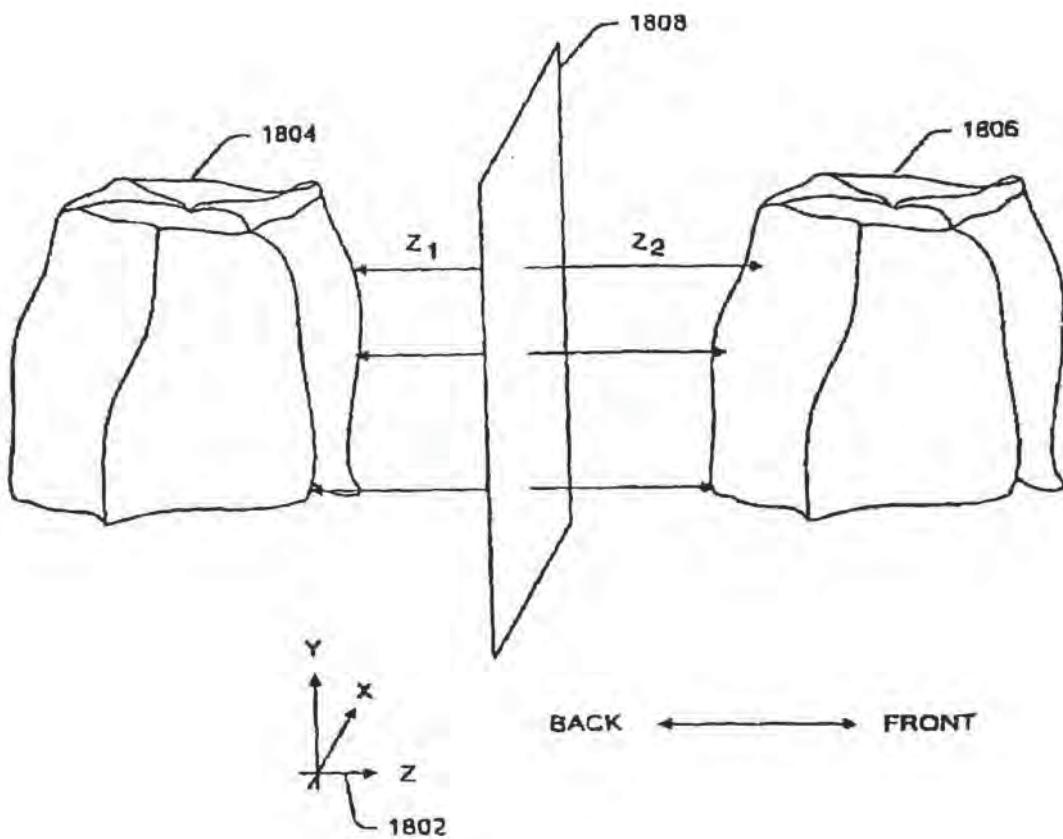


FIG. 18

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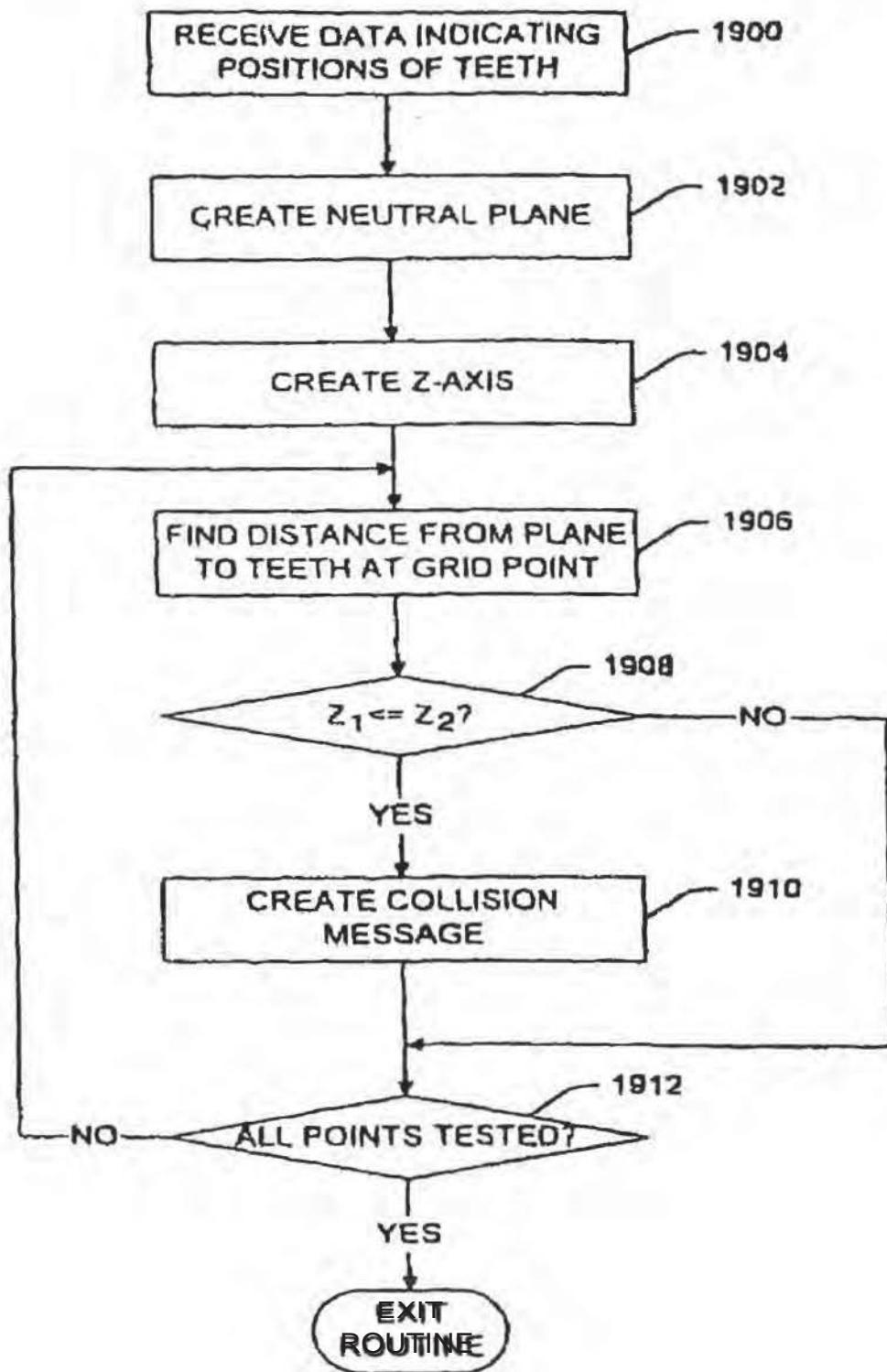


FIG. 19

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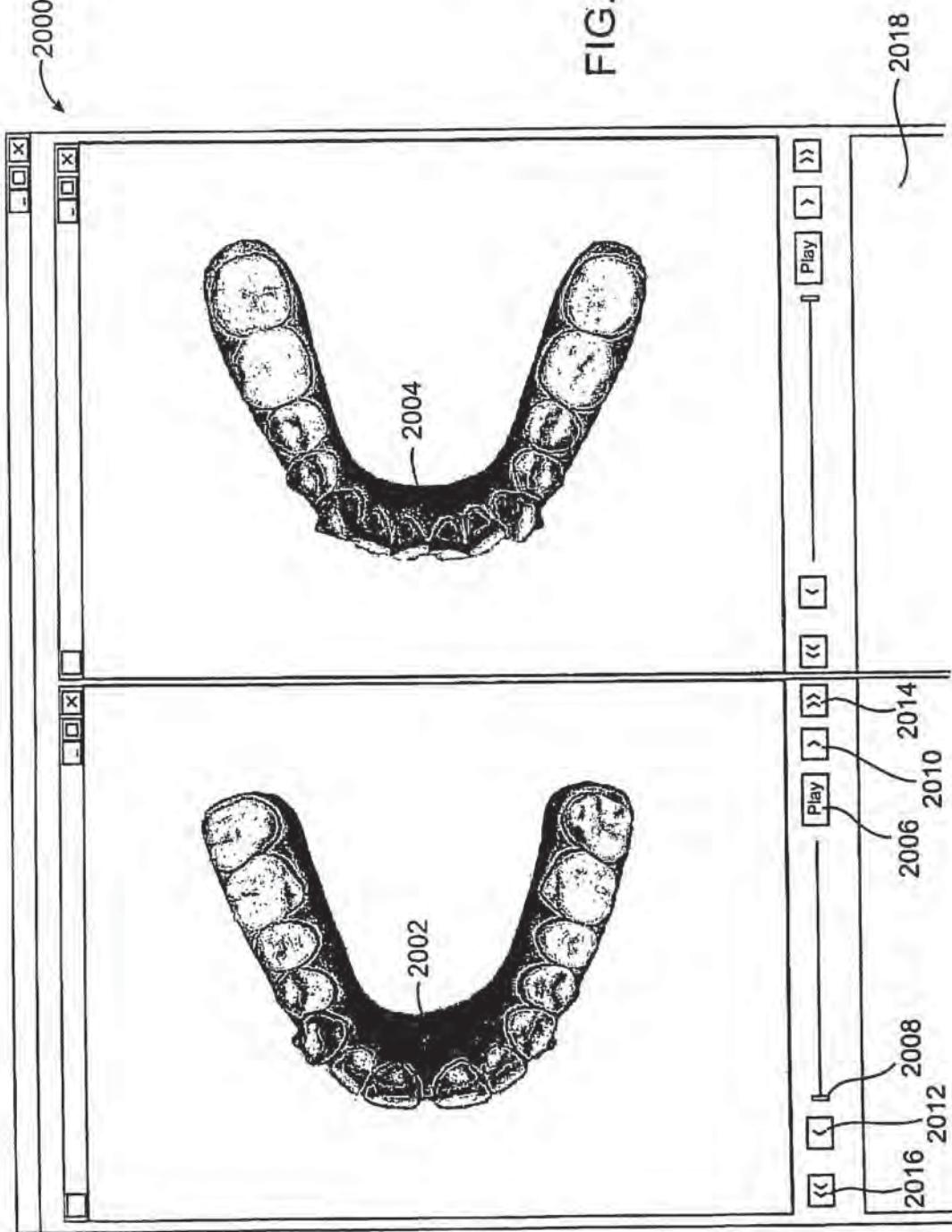
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FIG. 20



A3090

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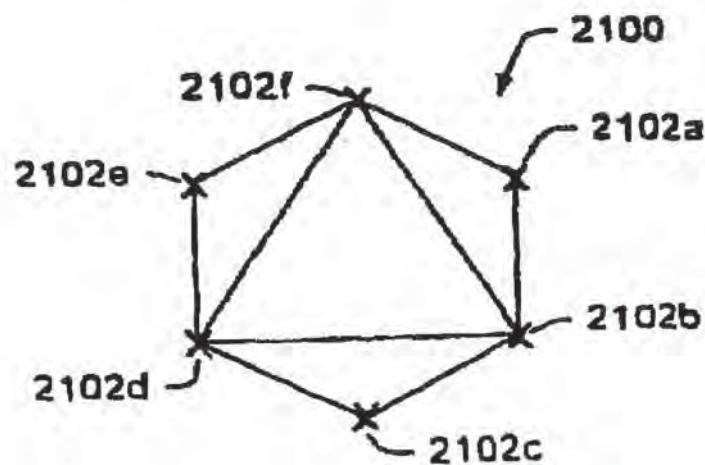


FIG. 2IA

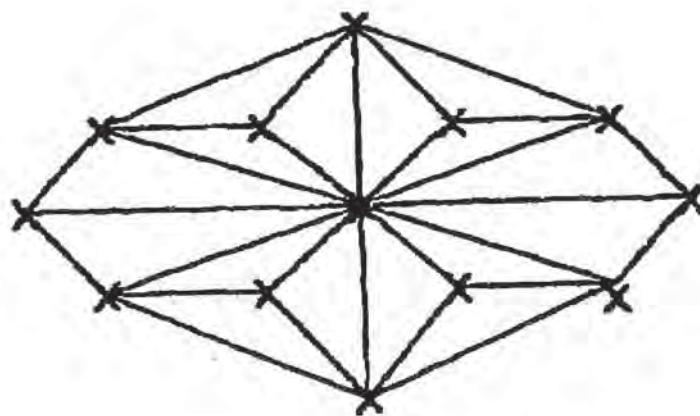


FIG. 2IB

A3091

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**COMPUTER AUTOMATED DEVELOPMENT
OF AN ORTHODONTIC TREATMENT PLAN
AND APPLIANCE**

**CROSS-REFERENCES TO RELATED
APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 09/686,190, filed Oct. 10, 2000, (now abandoned), which was a continuation of U.S. application Ser. No. 09/169,276, filed Oct. 8, 1998, (now abandoned), which is a continuation-in-part of PCT Application No. PCT/US/99/12691, filed on Jun. 19, 1998, which claimed priority from U.S. patent application Ser. No. 08/947,080, filed on Oct. 8, 1997, (now U.S. Pat. No. 5,975,893), which claims priority from U.S. Provisional Application No. 60/050,342, filed on Jun. 20, 1997, the full disclosures of which are incorporated in this application by reference.

This application is related to U.S. patent application Ser. No. 09/169,036, filed Oct. 8, 1998 (now U.S. Pat. No. 6,450,807) and U.S. patent application Ser. No. 09/169,034, filed Oct. 8, 1998, (now U.S. Pat. No. 6,471,511), both filed on Oct. 8, 1998, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates generally to the field of orthodontics and, more particularly, to computer automated development of an orthodontic treatment plan and appliance.

Repositioning teeth for aesthetic or other reasons is accomplished conventionally by wearing what are commonly referred to as "braces." Braces comprise a variety of appliances such as brackets, archwires, ligatures, and O-rings. Attaching the appliances to a patient's teeth is a tedious and time consuming enterprise requiring many meetings with the treating orthodontist. Consequently, conventional orthodontic treatment limits an orthodontist's patient capacity and makes orthodontic treatment quite expensive.

Before fastening braces to a patient's teeth, at least one appointment is typically possibly at a later meeting, an alginate mold of the patient's teeth is typically made. This mold provides a model of the patient's teeth that the orthodontist uses in conjunction with the X-rays and photographs to formulate a treatment strategy. The orthodontist then typically schedules one or more appointments during which braces will be attached to the patient's teeth.

At the meeting during which braces are first attached, the teeth surfaces are initially treated with a weak acid. The acid optimizes the adhesion properties of the teeth surfaces for brackets and bands that are to be bonded to them. The brackets and bands serve as anchors for other appliances to be added later. After the acid step, the brackets and bands are cemented to the patient's teeth using a suitable bonding material. No force-inducing appliances are added until the cement is set. For this reason, it is common for the orthodontist to schedule a later appointment to ensure that the brackets and bands are well bonded to the teeth.

The primary force-inducing appliance in a conventional set of braces is the archwire. The archwire is resilient and is attached to the brackets by way of slots in the brackets. The archwire links the brackets together and exerts forces on them to move the teeth over time. Twisted wires or elastomeric O-rings are commonly used to reinforce attachment of the archwire to the brackets. Attachment of the archwire to the brackets is known in the art of orthodontia as "ligation"

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and wires used in this procedure are called "ligatures." The elastomeric O-rings are called "plastics."

After the archwire is in place, periodic meetings with the orthodontist are required, during which the patient's braces will be adjusted by installing a different archwire having different force-inducing properties or by replacing or tightening existing ligatures. Typically, these meetings are scheduled every three to six weeks.

As the above illustrates, the use of conventional braces is a tedious and time consuming process and requires many visits to the orthodontist's office. Moreover, from the patient's perspective, the use of braces is unsightly, uncomfortable, presents a risk of infection, and makes brushing, flossing, and other dental hygiene procedures difficult.

For these reasons, it would be desirable to provide alternative methods and systems for repositioning teeth. Such methods and systems should be economical, and in particular should reduce the amount of time required by the orthodontist in planning and overseeing each individual patient. The methods and systems should also be more acceptable to the patient, in particular being less visible, less uncomfortable, less prone to infection, and more compatible with daily dental hygiene. At least some of these objectives will be met by the methods and systems of the present invention described hereinafter.

2. Description of the Background Art

Tooth positioners for finishing orthodontic treatment are described by Kesling in the *Am. J. Orthod. Oral. Surg.* 31:297-304 (1945) and 32:285-293 (1946). The use of silicone positioners for the comprehensive orthodontic realignment of a patient's teeth is described in Warunek et al. (1989) *J. Clin. Orthod.* 23:694-700. Clear plastic retainers for finishing and maintaining tooth positions are commercially available from Raintree Essix, Inc., New Orleans, La. 70125, and Tru-Tain Plastics, Rochester, Minn. 55902. The manufacture of orthodontic positioners is described in U.S. Pat. Nos. 5,186,623; 5,059,118; 5,055,039; 5,035,613; 4,856,991; 4,798,534; and 4,755,139.

Other publications describing the fabrication and use of dental positioners include Kleemann and Janssen (1996) *J. Clin. Orthodon.*, 30:673-680; Cureton (1996) *J. Clin. Orthodon.*, 30:390-395; Chiappone (1980) *J. Clin. Orthodon.*, 14:121-133; Shilliday (1971) *Am. J. Orthodontics*, 59:596-599; Wells (1970) *Am. J. Orthodontics*, 58:351-366; and Cottingham (1969) *Am. J. Orthodontics*, 55:23-31.

Kuroda et al. (1996) *Am. J. Orthodontics*, 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459.

U.S. Pat. Nos. 5,533,895; 5,474,448; 5,45-1,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, describe methods for manipulating digital images of teeth for designing orthodontic appliances.

U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the jaw is described in U.S. Pat. Nos. 5,342,202 and 5,340,309. Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429;

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4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

BRIEF SUMMARY OF THE INVENTION

In one aspect, the invention relates to the computer-automated creation of a plan for repositioning an orthodontic patient's teeth. A computer receives an initial digital data set representing the patient's teeth at their initial positions and a final digital data set representing the teeth at their final positions. The computer uses the data sets to generate treatment paths along which the teeth will move from the initial positions to the final positions.

In some implementations, the initial digital data set includes data obtained by scanning a physical model of the patient's teeth, such as by scanning a positive impression or a negative impression of the patient's teeth with a laser scanner or a destructive scanner. The positive and negative impression may be scanned while interlocked with each other to provide more accurate data. The initial digital data set also may include volume image data of the patient's teeth, which the computer can convert into a 3D geometric model of the tooth surfaces, for example using a conventional marching cubes technique. The computer also can be used to segment the initial digital data set automatically into individual tooth models, such as by performing a feature detection or matching operation on the image data. In some embodiments, the individual tooth models include data representing hidden tooth surfaces, such as roots imaged through x-ray, CT scan, or MRI techniques. Tooth roots and hidden surfaces also can be extrapolated from the visible surfaces of the patient's teeth.

In other embodiments, the computer applies a set of rules to detect collisions that will occur as the patient's teeth move along the treatment paths. One technique for collision detection is the creation of a collision buffer between two teeth at a given step along the treatment path. The computer also can be used to detect improper bite occlusions that will occur as the patient's teeth move along the treatment paths. Other embodiments allow the computer to render a three-dimensional (3D) graphical representation of the teeth at any selected treatment step. The computer also can be used to animate the graphical representation of the teeth to provide a visual display of the movement of the teeth along the treatment paths.

A VCR metaphor in the graphical user interface allows the user to control the animation. Level of detail compression can be used to improve the speed at with the 3D image of the teeth is rendered. Moreover, some embodiments allow the user to modify the underlying digital data set by repositioning a tooth in the 3D graphical representation.

In another aspect, the invention involves generating three-dimensional models of individual teeth from an initial data set that contains a 3D representation of a group of teeth. A computer performs this task by identifying points in the initial data set corresponding to each individual tooth and then segmenting the initial data set into multiple data sets, each containing the points identified for one of the teeth. In some embodiments, the computer stores each data set as a 3D geometric model representing the visible surfaces of the corresponding tooth. The computer can be used to modify each 3D model to include hidden surfaces of the corresponding tooth. In other embodiments, the initial data set contains digital volume image data, and the computer converts the volume image data into a 3D geometric model by detecting

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volume elements in the image data between which a sharp transition in digital image value occurs.

In another aspect, the invention relates to determining whether a patient's teeth can be moved from a first set of positions to a second set of positions. A computer performs this task by receiving a digital data set representing the teeth at the second set of positions and determining whether any of the teeth will collide while moving to the second set of positions. In some embodiments, the computer calculates distances between two of the teeth (a first tooth and a second tooth) by establishing a neutral projection plane between the first tooth and the second tooth, establishing a z-axis that is normal to the plane and that has a positive direction and a negative direction from each of a set of base points on the projection plane, computing a pair of signed distances comprising a first signed distance to the first tooth and a second signed distance to the second tooth, the signed distances being measured on a line passing through the base points and parallel to the z-axis, and determining that a collision will occur if any of the pair of signed distances indicates a collision.

In another aspect, the invention relates to determining final positions for an orthodontic patient's teeth. A computer receives a digital data set representing the teeth at recommended final positions, renders a three-dimensional (3D) graphical representation of the teeth at the recommended final positions, receives an instruction to reposition one of the teeth in response to a user's manipulation of the tooth in the graphical representation, and, in response to the instruction, modifies the digital data set to represent the teeth at the user-selected final positions.

In another aspect, the invention relates to analyzing a recommended treatment plan for an orthodontic patient's teeth. A computer receives a digital data set representing the patient's upper teeth after treatment, receives a digital data set representing the patient's lower teeth after treatment, orients the data in the data sets to simulate the patient's bite occlusion, manipulates the data sets in a manner that simulates motion of human jaws, and detects collisions between the patient's upper teeth and lower teeth during the simulation of motion. The simulation of motion can be based on observed motion of typical human jaws or the patient's jaws.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a patient's jaw and provides a general indication of how teeth may be moved.

FIG. 1B illustrates a single tooth from FIG. 1A and defines how tooth movement distances are determined.

FIG. 1C illustrates the jaw of FIG. 1A together with an incremental position adjustment appliance.

FIG. 2 is a block diagram illustrating steps for producing a system of incremental position adjustment appliances.

FIG. 3 is a block diagram setting forth the steps for manipulating an initial digital data set representing an initial tooth arrangement to produce a final digital data set corresponding to a desired final tooth arrangement.

FIG. 4A is a flow chart illustrating an eraser tool for the methods herein.

FIG. 4B illustrates the volume of space which is being erased by the program of FIG. 4A.

FIG. 5 is a flow chart illustrating a program for matching high-resolution and low resolution components in the manipulation of data sets of FIG. 3.

FIG. 6A is a flow chart illustrating a program for performing the "detection" stage of the cusp detection algorithm.

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FIG. 6B is a flow chart illustrating a program for performing the "rejection" stage of the cusp detection algorithm.

FIG. 7 illustrates a method for generating multiple intermediate digital data sets which are used for producing the adjustment appliances.

FIG. 8A is a flow chart illustrating the steps performed by the path scheduling algorithm.

FIG. 8B is a flow chart illustrating the steps for performing a "visibility" function.

FIG. 8C is a flow chart illustrating the steps for performing a "children" function.

FIG. 8D is a flow chart illustrating the steps for performing path scheduling step 128 of FIG. 8A.

FIG. 9A is a flow chart illustrating the steps for performing recursive collision testing during collision detection.

FIG. 9B is a flow chart illustrating node splitting performed during collision detection.

FIG. 9C is a flow chart illustrating steps for providing additional motion information to the collision detection process.

FIG. 10 illustrates alternative processes for producing a plurality of appliances utilizing digital data sets representing the intermediate and final appliance designs.

FIG. 11 is a simplified block diagram of a data processing system.

FIG. 12 is cross-sectional image of a plaster tooth casting in an epoxy mold.

FIG. 13 is a flow chart of a process for forming one 3D image data set of teeth from two sets of image data.

FIG. 14 is a flow chart of a process for forming a 3D surface mesh from 3D image data.

Figs. 15A, 15B, and 15C illustrate the positioning of teeth at various steps of an orthodontic treatment plan.

FIG. 16 is a flow chart of a process for determining a tooth's path among intermediate positions during an orthodontic treatment plan.

FIG. 17 is a flow chart of a process for optimizing the path of a tooth from an initial position to a final position during an orthodontic treatment plan.

FIG. 18 is a diagram illustrating a buffering technique for use in a collision detection algorithm.

FIG. 19 is a flow chart for a collision detection technique.

FIG. 20 is a screen shot of a GUI display used to render 3D images of an orthodontic patient's teeth.

Figs. 21A and 21B illustrate a technique for improving the downloading and rendering speed of an orthodontic image data file.

DETAILED DESCRIPTION OF THE INVENTION

Systems and methods are provided for moving teeth incrementally using a plurality of discrete appliances, where each appliance successively moves one or more of the patient's teeth by relatively small amounts. The tooth movements will be those normally associated with orthodontic treatment, including translation in all three orthogonal directions relative to a vertical centerline, rotation of the tooth centerline in the two orthodontic directions ("root angulation" and "torque"), as well as rotation about the centerline.

Referring now to FIG. 1A, a representative jaw 100 includes sixteen teeth, at least some of which are to be moved from an initial tooth arrangement to a final tooth arrangement. To understand how the teeth may be moved, an arbitrary centerline (CL) is drawn through one of the teeth 102. With reference to this centerline (CL), the teeth may be

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moved in the orthogonal directions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally, the tooth may be rotated about the centerline, as represented by arrow 114. Thus, all possible free-form motions of the tooth can be performed.

Referring now to FIG. 1B, the magnitude of any tooth movement is defined in terms of the maximum linear translation of any point P on a tooth 102. Each point P_i will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in FIG. A. That is, while the point will usually follow a non-linear path, there will be a linear distance between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P_i may in fact undergo a true side-to-side translation as indicated by arrow d₁, while a second arbitrary point P₂ may travel along an arcuate path, resulting in a final translation d₂. In many situations, the maximum permissible movement of a point P_i in any particular tooth is defined as the maximum linear translation of that point P_i on the tooth which undergoes the maximum movement for that tooth in any treatment step.

One tool for incrementally repositioning the teeth in a patient's jaw is a set of one or more adjustment appliances. Suitable appliances include any of the known positioners, retainers, or other removable appliances which are used for finishing and maintaining teeth positions in connection with conventional orthodontic treatment. As described below, a plurality of such appliances can be worn by a patient successively to achieve gradual tooth repositioning. A particularly advantageous appliance is the appliance 100, shown in FIG. 1C, which typically comprises a polymeric shell having a cavity shaped to receive and resiliently reposition teeth from one tooth arrangement to another tooth arrangement. The polymeric shell typically fits over all teeth present in the upper or lower jaw. Often, only some of the teeth will be repositioned while others will provide a base or anchor region for holding the repositioning appliance in place as it applies the resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, many or most of the teeth will be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance. The gums and the palette also serve as an anchor region in some cases, thus allowing all or nearly all of the teeth to be repositioned simultaneously.

The polymeric appliance 100 of FIG. 1C is preferably formed from a thin sheet of a suitable elastomeric polymeric, such as Tru-Tain 0.03 in. thermal forming dental material, marketed by Tru-Tain Plastics, Rochester, Minn. 55902. In many cases, no wires or other means are provided for holding the appliance in place over the teeth. In some cases, however, it is necessary to provide individual attachments on the teeth with corresponding receptacles or apertures in the appliance 100 so that the appliance can apply forces that would not be possible or would be difficult to apply in the absence of such attachments.

Building a Digital Model of the Patient's Teeth
Gathering Data About the Teeth

Referring now to FIG. 2, a method for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth will be described. As a first step, a digital data set representing an initial tooth arrangement is obtained, referred to hereinafter as the initial digital data set, or IDDS. The IDDS may be obtained in a variety of ways. For example, the patient's

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teeth may be scanned or imaged using well known technology, such as X-rays, three-dimensional X-rays, computer-aided tomographic images or data sets, and magnetic resonance images. Methods for digitizing such conventional images to produce useful data sets are well known and described in the patent and medical literature. Usually, however, a plaster cast of the patient's teeth is obtained by well known techniques, such as those described in Gruber, Orthodontics: Principle and Practice, Second Edition, Saunders, Philadelphia, 1969, pp. 401-415.

After the tooth casting is obtained, the casting is digitally scanned by a scanner, such as a non-contact type laser or destructive scanner or a contact-type scanner, to produce the IDDS. The data set produced by the scanner may be presented in any of a variety of digital formats to ensure compatibility with the software used to manipulate images represented by the data, as described in more detail below. General techniques for producing plaster casts of teeth and generating digital models using laser scanning techniques are described, for example, in U.S. Pat. No. 5,605,459, the full disclosure of which is incorporated in this application by reference.

Suitable scanners include a variety of range acquisition systems, generally categorized by whether the acquisition process requires contact with the three dimensional object being scanned. Some contact-type scanners use probes having multiple degrees of translational and/or rotational freedom. A computer-readable (i.e., digital) representation of the sample object is generated by recording the physical displacement of the probe as it is drawn across the sample surface.

Conventional non-contact-type scanners include reflective-type and transmissive-type systems. A wide variety of reflective systems are in use today, some of which utilize non-optical incident energy sources such as microwave radar or sonar. Others utilize optical energy. Non-contact-type systems that use reflected optical energy usually include special instrumentation that carry out certain measuring techniques (e.g., imaging radar, triangulation and interferometry).

One type of non-contact scanner is an optical, reflective scanner, such as a laser scanner. Non-contact scanners such as this are inherently nondestructive (i.e., do not damage the sample object), generally are characterized by a relatively high capture resolution, and are capable of scanning a sample in a relatively short period of time. One such scanner is the Cyberware, Model 15 scanner manufactured by Cyberware, Inc., Monterey, Calif.

Both non-contact-type and contact-type scanners also can include color cameras which, when synchronized with the scanning capabilities, provide means for capturing, in digital format, color representations of the sample objects. The importance of this ability to capture not just the shape of the sample object but also its color is discussed below.

Other scanners, such as the CSS-1000 model destructive scanner produced by Capture Geometry Inside (CGI), Minneapolis, Minn., can provide more detailed and precise information about a patient's teeth than a typical range acquisition scanner can provide. In particular, a destructive scanner can image areas that are hidden or shielded from a range acquisition scanner and therefore may not be subject to adequate imaging. The CSS-1000 scanner gathers image data for an object by repeatedly milling thin slices from the object and optically scanning the sequence of milled surfaces to create a sequence of 2D image slices, so none of the object's surfaces are hidden from the scanner. Image processing software combines the data from individual slices to

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form a data set representing the object, which later is converted into a digital representation of the surfaces of the object, as described below.

The destructive scanner may be used in conjunction with a laser scanner to create a digital model of a patient's teeth. For example, a laser scanner may be used first to build a low resolution image of a patient's upper and lower arches coupled with the patient's wax bite, as described below. The destructive scanner then may be used to form high-resolution images of the individual arches. The data obtained by the laser scanner indicates the relation between the patient's upper and lower teeth which later can be used to relate to each other the images generated by the destructive scanner and the digital models derived from them.

The destructive scanner can be used to form the initial digital data set (IDDS) of the patient's teeth by milling and scanning a physical model, such as a plaster casting, of the teeth. To ensure a consistent orientation of the casting throughout the destructive scanning process, a scanning system operator pots the casting in potting material, such as Encase-It epoxy from CGI, and cures the material in a pressure vacuum (PV) chamber to form a mold. Placing the potting material into the PV chamber ensures that the material sets relatively quickly with virtually no trapped air bubbles. The color of the potting material is selected to contrast sharply with the color of the casting material to ensure the clarity of the scanned image. The operator, then mounts the mold to a mounting plate and places the molding plate in the destructive scanning system.

A slicing mechanism ("cutter") in the destructive scanning system mills a thin slice (typically between 0.001" and 0.006" thick) from the mold, and a positioning arm places the milled surface near an optical scanner. The optical scanner, which may be an off-the-shelf device such as a flatbed scanner or a digital camera, scans the surface to create a 2D image data set representing the surface. The positioning arm then repositions the mold below the cutter, which again mills a thin slice from mold. The resulting output of the destructive scanning system is a 3D image data set, which later is converted into a digital model of surfaces, as described in detail below. A destructive scanning system and the corresponding destructive scanning and data processing are described in U.S. Pat. No. 5,621,648.

FIG. 12 shows a scanned image 1200 of an exposed surface of a plaster tooth casting 1202 embedded in an epoxy mold 1204. The black color of the epoxy mold 1204 provides sharp contrast with the white color of the plaster casting 1202. An orientation guide 1206 appears in a corner of each image slice to ensure proper alignment of the image data after the destructive scan. The orientation guide 1206 can include a rigid structure, such as a piece of PVC tubing, embedded in the mold 1204.

A patient's wax bite can be used to acquire the relative positions of the upper and lower teeth in centric occlusion. For a laser scan, this can be accomplished by first placing the lower cast in front of the scanner, with the teeth facing upwards, then placing the wax bite on top of the lower cast, and finally placing the upper cast on top of the lower cast, with the teeth facing downwards, resting on the wax bite. A cylindrical scan is then acquired for the lower and upper casts in their relative positions. The scanned data provides a digital model of medium resolution representing an object which is the combination of the patient's arches positioned in the same relative configuration as in the mouth.

The digital model acts as a template guiding the placement of the two individual digital models (one per arch). More precisely, using software, for example the CyberWare

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alignment software, each digital arch is in turn aligned to the pair scan. The individual models are then positioned relative to each other corresponding to the arches in the patient's mouth.

The waxbite can also be scanned separately to provide a second set of data about the teeth in the upper and lower arches. In particular, the plaster cast provides a "positive" image of the patient's teeth, from which one set of data is derived, and the waxbite provides a "negative" image of the teeth, from which a second, redundant set of data is derived. The two sets of data can then be matched to form a single data set describing the patient's teeth with increased accuracy and precision. The impression from which the plaster cast was made also can be used instead of or in addition to the waxbite.

FIG. 13 is a flow chart of a process for deriving a single set of data from a positive data set and a negative data set. First, scan data representing positive and negative physical tooth models is obtained (steps 1300, 1302). If the scan data was acquired through a destructive scanning process, two digital 3D geometric models are constructed from the data, as described below (step 1304). Scan data acquired from an optical or range acquisition scanner system typically suffices as a geometric model. One of the geometric models is positioned to match roughly with the other model in the digital model space (step 1306), and an optimization process is performed to determine the best match between the models (step 1308). The optimization process attempts to match one point in each model to one point in the other model. Each pair of matched points then is combined into a single point to form a single set of data (step 1310). The combining of matched points can be carried out in a variety of ways, for example, by averaging the coordinates of the points in each pair.

While a laser scanning system typically must perform three scans to image a patient's full set of teeth adequately (one high resolution scan for each of the upper and lower casts and a medium resolution waxbite scan), the destructive scanning system described above can image a patient's full set of teeth adequately with only a single waxbite scan. Scanning both casts with the wax bite in place ensures that all important surfaces of the upper and lower teeth are captured during a destructive scan. Scanning both casts in this manner also provides a high resolution image data set that preserves the relation between the patient's upper and lower teeth. Like the potting material described above, the wax bite should have a color that contrasts sharply with the color of the casting material to ensure the clarity of the scanned image. The wax bite may be the same color as the potting material if no contrast is desired between the waxbite and the potting material. Alternatively, the color of the wax bite may contrast sharply with the tooth casts and the potting material if an image of the wax bite is needed.

In addition to the 3D image data gathered by laser scanning or destructive scanning the exposed surfaces of the teeth, a user may wish to gather data about hidden features, such as the roots of the patient's teeth and the patient's jaw bones. This information is used to build a more complete model of the patient's dentition and to show with more accuracy and precision how the teeth will respond to treatment. For example, information about the roots allows modeling of all tooth surfaces, instead of just the crowns, which in turn allows simulation of the relationships between the crowns and the roots as they move during treatment. Information about the patient's jaws and gums also enables a more accurate model of tooth movement during treatment. For example, an x-ray of the patient's jaw bones can assist

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in identifying ankylose teeth, and an MRI can provide information about the density of the patient's gum tissue. Moreover, information about the relationship between the patient's teeth and other cranial features allows accurate alignment of the teeth with respect to the rest of the head at each of the treatment steps. Data about these hidden features may be gathered from many sources, including 2D and 3D x-ray systems, CT scanners, and magnetic resonance imaging (MRI) systems. Using this data to introduce visually hidden features to the tooth model is described in more detail below.

Developing an orthodontic treatment plan for a patient involves manipulating the IDDS at a computer or workstation having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. Specific aspects of the software will be described in detail hereinafter. However, dental appliances having incrementally differing geometries can be produced by non-computer-aided techniques. For example, plaster casts obtained as described above may be cut using knives, saws, or other cutting tools in order to permit repositioning of individual teeth within the casting. The disconnected teeth may then be held in place by soft wax or other malleable material, and a plurality of intermediate tooth arrangements can then be prepared using such a modified plaster casting of the patient's teeth. The different arrangements can be used to prepare sets of multiple appliances, generally as described below, using pressure and vacuum molding techniques.

Creating a 3D Surface Model of the Teeth

Many types of scan data, such as that acquired by an optical scanning system, provide a 3D geometric model (e.g., a triangular surface mesh) of the teeth when acquired. Other scanning techniques, such as the destructive scanning technique described above, provide data in the form of volume elements ("voxels") that can be converted into a digital geometric model of the tooth surfaces.

FIG. 14 is a flowchart of a process for forming a surface mesh from voxel image data. This approach involves receiving the image data from the destructive scanner (step 1400), processing the data to isolate the object to be modeled (step 1401), and applying a conventional "marching cubes" technique to create a surface mesh of the object (step 1402).

Each set of image data can include images of multiple tooth casts or of a tooth cast and extraneous, "noisy" objects, such as air bubbles in the potting material. The system identifies each object in the image by assigning each voxel a single-bit binary value (e.g., "0" for black and "1" for white) based on the voxel's 8-bit gray scale image value, and then connecting adjacent voxels that have been assigned the same single-bit value. Each group of connected voxels represents one of the objects in the image. The system then isolates the tooth casting to be modeled by masking from the image all objects except the tooth casting of interest. The system removes noise from the masked image data by passing the data through a low-pass filter.

Once the tooth casting is isolated from the image data, the system performs a conventional marching cubes technique to locate tooth and tissue surfaces in the image data. This technique involves the identification of pairs of adjacent voxels having 8-bit image values that fall on opposite sides of a selected threshold value. Specifically, each voxel has an associated image value typically a number between 0 and 255 that represents the image color or gray scale value at that voxel. Because the tooth casting and the surrounding potting material have sharply contrasting colors (see FIG. 12), the image values at voxels forming the image of the tooth casting differ greatly from the values at voxels forming the

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image of the surrounding material. Therefore, the marching cube algorithm, can locate the tooth surfaces by identifying the voxels at which a sharp transition in image value occurs. The algorithm can position the surface precisely between two voxels by determining the difference between the threshold value and the image value at each voxel and then placing the surface a corresponding distance from the centerpoint of each voxel.

In some implementations, after the marching cubes algorithm is applied, the resulting mesh undergoes a smoothing operation to reduce the jaggedness on the surfaces of the tooth model caused by the marching cubes conversion (step 1404). A conventional smoothing operation can be used, such as one that moves individual triangle vertices to positions representing the averages of connected neighborhood vertices to reduce the angles between triangles in the mesh.

Another optional step is the application of a decimation operation to the smoothed mesh to eliminate data points, which improves processing speed (step 1406). Conventional decimation operations identify pairs of triangles that lie almost in the same plane and combine each identified pair into a single triangle by eliminating the common vertex. The decimation operation used here also incorporates orthodontic-specific decimation rules, which rely on an understanding of the general characteristics of the teeth and gums and of the orthodontic appliances that will be used to carry out a treatment plan. For example, aligners typically do not contact the portions of the tooth surfaces adjacent to the gums, so these tooth surfaces can be modeled less accurately than the rest of the tooth. The decimation operation incorporates this knowledge by decimating more heavily along the gum line. When an appliance such as a polymeric shell aligner will be used to treat the patient's teeth, the algorithm also decimates more heavily on the sides of the teeth, where the aligner usually is required only to push orthogonally to the surface, than it decimates on the tops of the teeth, where the aligner usually must form a solid grip.

After the smoothing and decimation operation are performed, an error value is calculated based on the differences between the resulting mesh and the original mesh or the original data (step 1408), and the error is compared to an acceptable threshold value (step 1410). The smoothing and decimation operations are applied to the mesh once again if the error does not exceed the acceptable value. The last set of mesh data that satisfies the threshold is stored as the tooth model (step 1412).

Creating 3D Models of the Individual Teeth

Once a 3D model of the tooth surfaces has been constructed, models of the patient's individual teeth can be derived. In one approach, individual teeth and other components are "cut" to permit individual repositioning or removal of teeth in or from the digital data. After the components are "freed," a prescription or other written specification provided by the treating professional is followed to reposition the teeth. Alternatively, the teeth may be repositioned based on the visual appearance or based on rules and algorithms programmed into the computer. Once an acceptable final arrangement has been created, the final tooth arrangement is incorporated into a final digital data set (FDDS).

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDDS's) are generated to correspond to successive intermediate tooth arrangements. The system of incremental position adjustment appliances can then be fabricated based on the INTDDDS's, as described in more detail below. Segmentation of individual teeth from

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the tooth model and determining the intermediate and final positions of teeth also are described in more detail below.

Simplifying the 3D Model

FIG. 3 illustrates a representative technique for user-assisted manipulation of the IDDS to produce the FDDS on the computer. Usually, the data from the digital scanner is acquired in high resolution form. In order to reduce the computer time necessary to generate images, a parallel set of digital data representing the IDDS at a lower resolution can be created. The user can manipulate the lower resolution images while the computer updates the high resolution data set as necessary. The user can also view and manipulate the high resolution model if the extra detail provided in that model is useful. The IDDS also can be converted into a quad edge data structure if not already present in that form. A quad edge data structure is a standard topological data structure defined in *Primitives for the Manipulation of General Subdivisions and the Computation of Voronoi Diagrams*, ACM Transactions of Graphics, Vol. 4, No. 2, April 1985, pp. 74-123. Other topological data structures, such as the winged-edge data structure, could also be used.

As an initial step, while viewing the three-dimensional image of the patient's jaw, including the teeth, gingivae, and other oral tissue, the user usually deletes structure which is unnecessary for image manipulation and final production of an appliance. These unwanted sections of the model may be removed using an eraser tool to perform a solid modeling subtraction. The tool is represented by a graphic box. The volume to be erased (the dimensions, position, and orientation of the box) are set by the user employing the GUI. Typically, unwanted sections would include extraneous gum area and the base of the originally scanned cast. Another application for this tool is to stimulate the extraction of teeth and the "shaving down" of tooth surfaces. This is necessary when additional space is needed in the jaw for the final positioning of a tooth to be moved. The treating professional may choose to determine which teeth will be shaved and which teeth will be extracted. Shaving allows the patient to maintain teeth when only a small amount of space is needed. Typically, extraction and shaving are used in the treatment planning only when the actual patient teeth are to be extracted or shaved prior to initiating repositioning.

Removing unwanted or unnecessary sections of the model increases data processing speed and enhances the visual display. Unnecessary sections include those not needed for creation of the tooth repositioning appliance. The removal of these unwanted sections reduces the complexity and size of the digital data set, thus accelerating manipulations of the data set and other operations.

After the user positions and sizes the eraser tool and instructs the software to erase the unwanted section, all triangles within the box set by the user are removed and the border triangles are modified to leave a smooth, linear border. The software deletes all of the triangles within the box and clips all triangles which cross the border of the box. This requires generating new vertices on the border of the box. The holes created in the model at the faces of the box are rettriangulated and closed using the newly created vertices.

In alternative embodiments, the computer automatically simplifies the digital model by performing the user-oriented functions described above. The computer applies a knowledge of orthodontic relevance to determine which portions of the digital model are unnecessary for image manipulation.

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Segmenting the Teeth in the 3D Model

Human-Assisted Segmentation

The saw tool is used to define the individual teeth (or possibly groups of teeth) to be moved. The tool separates the scanned image into individual graphic components enabling the software to move the tooth or other component images independent of remaining portions of the model. In one embodiment, the saw tool defines a path for cutting the graphic image by using two cubic B-spline curves lying in space, possibly constrained to parallel planes, either open or closed. A set of lines connects the two curves and shows the user the general cutting path. The user may edit the control points on the cubic B-splines, the thickness of the saw cut, and the number of erasers used, as described below.

In an alternative embodiment, the teeth are separated by using the saw as a "coring" device, cutting the tooth from above with vertical saw cuts. The crown of the tooth, as well as the gingivae tissue immediately below the crown are separated from the rest of the geometry, and treated as an individual unit, referred to as a tooth. When this model is moved, the gingivae tissue moves relative to the crown, creating a first order approximation of the way that the gingivae will reform within a patient's mouth.

Each tooth may also be separated from the original trimmed model. Additionally, a base may be created from the original trimmed model by cutting off the crowns of the teeth. The resulting model is used as a base for moving the teeth. This facilitates the eventual manufacture of a physical mold from the geometric model, as described below.

Thickness: When a cut is used to separate a tooth, the user will usually want the cut to be as thin as possible. However, the user may want to make a thicker cut, for example, when shaving down surrounding teeth, as described above. Graphically, the cut appears as a curve bounded by the thickness of the cut on one side of the curve.

Number of Erasers: A cut is comprised of multiple eraser boxes arranged next to each other as a piecewise linear approximation of the Saw Tool's curve path. The user chooses the number of erasers, which determines the sophistication of the curve created: the greater the number of segments, the more accurately the cutting will follow the curve. The number of erasers is shown graphically by the number of parallel lines connecting the two cubic B-spline curves. Once a saw cut has been completely specified the user applies the cut to the model. The cut is performed as a sequence of erasings, as shown in FIG. 4A. FIG. 4B shows a single erasing iteration of the cut as described in the algorithm for an open ended B-spline curve. For a vertical cut, the curves are closed, with $P_A[O]$ and $P_A[S]$ being the same point and $P_B[O]$ and $P_B[S]$ being the same point.

In one embodiment, the software may automatically partition the saw tool into a set of erasers based upon a smoothness measure input by the user. The saw is adaptively subdivided until an error metric measures the deviation from the ideal representation to the approximate representation to be less than a threshold specified by the smoothness setting. One error metric compares the linear length of the subdivided curve to the arclength of the ideal spline curve. When the difference is greater than a threshold computed from the smoothness setting, a subdivision point is added along the spline curve.

A preview feature may also be provided in the software. The preview feature visually displays a saw cut as the two surfaces that represent opposed sides of the cut. This allows the user to consider the final cut before applying it to the model data set.

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After the user has completed all desired cutting operations with the saw tool, multiple graphic solids exist. However, at this point, the software has not determined which triangles of the quad edge data structure belong to which components.

5 The software chooses a random starting point in the data structure and traverses the data structure using adjacency information to find all of the triangles that are attached to each other, identifying an individual component. This process is repeated starting with the triangle whose component is not yet determined. Once the entire data structure is traversed, all components have been identified.

To the user, all changes made to the high resolution model appear to occur simultaneously in the low resolution model, and vice versa. However, there is not a one-to-one correlation between the different resolution models. Therefore, the computer "matches" the high resolution and low resolution components as best as it can subject to defined limits. One process for doing so is described in FIG. 5.

Automated Segmentation

20 The system can optionally include a segmentation subsystem that performs automatic or semi-automatic segmentation of the 3D dentition model into models of individual teeth. The segmentation subsystem is advantageously implemented as one or more computer program processes imple-

25 ments a segmentation process. In alternative implementations, the segmentation process can act on the 3D volume data or on the 3D surface mesh. The segmentation process applies conventional feature detection techniques tailored to exploit the characteristics and known features of teeth. For

30 example, feature detection algorithms generally act on images in which the features to be distinguished from each other have different colors or shades of gray. Features to be detected also usually are separated spatially from each other. However, features to be detected in a 2D or 3D image of a 35 plaster tooth casting (e.g., the individual teeth and the gum tissue) all have the same color (white), and some features, such as an individual tooth and the surrounding gum tissue, have no spacial separation.

The segmentation process can be implemented to employ 40 any of several feature detection techniques and advantageously uses a combination of techniques to increase the accuracy of feature identification. One feature detection technique uses color analysis to distinguish objects based on variations in color. Color analysis can be used in situations 45 where individual teeth are separated by gaps large enough for the potting material to fill. Because the tooth casting and the potting material have contrasting colors, these teeth appear in the model as white areas separated by thin strips of black.

50 Another feature detection technique uses shape analysis to distinguish certain features, such as tooth from gum. In general, tooth surfaces are smooth while gum surfaces have texture, and teeth and gums typically form a U-shaped ridge where they meet. Detecting these features through shape 55 analysis assists in distinguishing tooth from gum. Shape analysis can also detect individual teeth, for example by searching for the largest objects in the 3D image or by recognizing the cusps of a molar as four isolated patches of one color arranged in a certain pattern. One cusp-detection algorithm is described below.

Other feature detection techniques use databases of known cases or statistical information against which a particular 60 65 3D image is matched using conventional image pattern matching and data fitting techniques. One such technique, known as "Maximum posteriori" (MAP), uses prior images to model pixel values corresponding to distinct object types (classes) as independent random variables with

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normal (Gaussian) distributions whose parameters (mean and variance) are selected empirically. For each class, a histogram profile is created based on a Gaussian distribution with the specified mean and variance. The prior images supply for each pixel and each class the probability that the pixel belongs to the class, a measure which reflects the relative frequency of each class. Applying Bayes' Rule to each class, the pixel values in the input image are scaled according to the prior probabilities, then by the distribution function. The result is a posterior probability that each pixel belongs to each class. The Maximum a posteriori (MAP) approach then selects for each pixel the class with the highest posterior probability as the output of the segmentation.

Another feature detection technique uses automatic detection of tooth cusps. Cusps are pointed projections on the chewing surface of a tooth. In one implementation, cusp detection is performed in two stages: (1) a "detection" stage, during which a set of points on the tooth are determined as candidates for cusp locations; and (2) a "rejection" stage, during which candidates from the set of points are rejected if they do not satisfy a set of criteria associated with cusps.

One process for the "detection" stage is set forth in FIG. 6A. In the detection stage, a possible cusp is viewed as an "island" on the surface of the tooth, with the candidate cusp at the highest point on the island. "Highest" is measured with respect to the coordinate system of the model, but could just as easily be measured with respect to the local coordinate system of each tooth if detection is performed after the cutting phase of treatment.

The set of all possible cusps is determined by looking for all local maxima on the tooth model that are within a specified distance of the top of the bounding box of the model. First, the highest point on the model is designated as the first candidate cusp. A plane is passed through this point, perpendicular to the direction along which the height of a point is measured. The plane is then lowered by a small predetermined distance along the Z axis. Next, all vertices connected to the tooth and which are above the plane and on some connected component are associated with the candidate cusp as cusps. This step is also referred to as the "flood fill" step. From each candidate cusp point, outward "flooding" is performed, marking each vertex on the model visited in this manner as "part of the corresponding candidate cusp." After the flood fill step is complete, every vertex on the model is examined. Any vertex that is above the plane and has not been visited by one of the flood fills is added to the list of candidate cusps. These steps are repeated until the plane is traveled a specified distance.

While this iterative approach can be more time consuming than a local maximum search, the approach described above leads to a shorter list of candidate cusps. Since the plane is lowered a finite distance at each step, very small local maxima that can occur due to noisy data are skipped over.

After the "detection" stage, the cusp detection algorithm proceeds with the "rejection" stage. One process for the "rejection" stage is set forth in FIG. 6B. In this stage, the local geometries around each of cusp candidates are analyzed to determine if they possess "non-cusplike features." Cusp candidates that exhibit "non-cusp-like features" are removed from the list of cusp candidates.

Various criteria may be used to identify "non-cusp-like features." According to one test, the local curvature of the surface around the cusp candidate is used to determine whether the candidate possesses non-cusp-like features. As depicted in FIG. 6B, the local curvature of the surface around the cusp candidate is approximated and then ana-

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lyzed to determine if it is too large (very pointy surface) or too small (very flat surface), in which case the candidate is removed from the list of cusp candidates. Conservative values are used for the minimum and maximum curvature values to ensure that genuine cusps are not rejected by mistake.

Under an alternative test, a measure of smoothness is computed based on the average normal in an area around the candidate cusp. If the average normal deviates from the normal at the cusp by more than a specified amount, the candidate cusp is rejected. In one embodiment, the deviation of a normal vector N from the cusp normal CN is approximated by the formula:

$$\text{deviation} = 1 - \text{Abs}(N \cdot C)$$

which is zero at no deviation, and 1 when N and CN are perpendicular.

For both the human-assisted and automated segmentation techniques, the clinician can simplify the tooth identification process by marking the physical tooth model before the model is scanned. Upon scanning, these marks become part of the digital tooth model. The types of marks that the clinician might use include marks identifying the rotational axis of a tooth, marks identifying the principal axis of a tooth (e.g., a straight line marked on the tooth's occlusal edge), and marks identifying the boundaries between teeth. A mark identifying the rotational axis of a tooth often is used to restrict how the tooth can rotate during the course of treatment. The clinician also may wish to paint the teeth in the physical model with various colors to assist in segmenting the individual teeth from the digital tooth model.

Adding Roots and Hidden Tooth Surfaces to the Individual Tooth Models

The system can optionally be configured to add roots and hidden surfaces to the tooth models to allow more thorough and accurate simulation of tooth movement during treatment. In alternative implementations, this information is added automatically without human assistance, semi-automatically with human assistance, or manually by human operator, using a variety of data sources.

In some implementations, 2D and 3D imaging systems, such as x-ray systems, computed tomography (CT) scanners, and MRI systems, are used to gather information about the roots of the patient's teeth. For example, several 2D x-ray images of a tooth taken in different planes allow the construction of a 3D model of the tooth's roots. Information about the roots is available by visual inspection of the x-ray image and by application of a computer-implemented feature identification algorithm to the x-ray data. The system adds the roots to the tooth model by creating a surface mesh representing the roots. Physical landmarks on the patient's teeth, e.g., cavities or cusps, are extracted from the 2D and 3D data and are used to register the roots to the tooth model. Like the roots, these landmarks can be extracted manually or by use of a feature detection algorithm.

Another alternative for the addition of roots and hidden surfaces is to model typical root and crown shapes and to modify the digital model of each tooth to include a root or a hidden surface corresponding to a typical shape. This approach assumes that the roots and hidden surfaces of each patient's teeth have typical shapes. A geometric model of each typical shape is acquired, e.g., by accessing an electronic database of typical root and crown models created before the analysis of a particular patient's teeth begins.

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Portions of the typical root and crown models are added to the individual tooth models as needed to complete the individual tooth models.

Yet another alternative for the addition of roots and hidden surfaces is the extrapolation of the 3D tooth model to include these features based on observed characteristics of the tooth surfaces. For example, the system can use the curvature of a particular molar between the tips of the cusps and the gumline to predict the shape of the roots for that molar. In other implementations, x-ray and CT scan data of a patient's teeth are used to provide comparison points for extrapolation of the patients roots and hidden surfaces. Models of typical root and crown shapes also can be used to provide comparison points for root and hidden surface extrapolation.

Determining the Final Tooth Positions

Once the teeth have been separated, the FDDS can be created from the IDDS. The FDDS is created by following the orthodontists' prescription to move the teeth in the model to their final positions. In one embodiment, the prescription is entered into a computer, which automatically computes the final positions of the teeth. In alternative other embodiments, a user moves the teeth into their final positions by independently manipulating one or more teeth while satisfying the constraints of the prescription. Various combinations of the above described techniques may also be used to arrive at the final tooth positions.

One method for creating the FDDS involves moving the teeth in a specified sequence. First, the centers of each of the teeth are aligned to a standard arch. Then, the teeth are rotated until their roots are in the proper vertical position. Next, the teeth are rotated around their vertical axis into the proper orientation. The teeth are then observed from the side, and translated vertically into their proper vertical position. The inclusion of roots in the tooth models, described more fully above, ensures the proper vertical orientation of the entire tooth, not just the crown. Finally, the two arches are placed together, and the teeth moved slightly to ensure that the upper, and lower arches properly mesh together. The meshing of the upper and lower arches together is visualized using a collision detection process to highlight the contacting points of the teeth in red.

Apart from its role in identifying individual teeth, cusp detection also is useful in determining final tooth orientation. For example, the cusps on a typical molar are relatively level when the tooth is oriented vertically, so the relative positions of the cusp tips indicate the tooth's position. Cusp detection therefore is incorporated into the final position determination.

One tool for use in visualizing the interaction of a patient's upper and lower teeth at the final positions is a computer-implemented "virtual" articulator. The virtual articulator provides a graphical display that simulates the operation of the patient's jaw or the operation of a conventional mechanical articulator attached to a physical model of the patient's teeth. In particular, the virtual articulator orients the digital models of the patient's upper and lower arches in the same manner that the patient's physical arches will be oriented in the patient's mouth at the end of treatment. The articulator then moves the arch models through a range of motions that simulate common motions of the human jaw.

The quality of the virtual articulator's simulation depends on the types of information used to create the articulator and the tooth models. In some implementations, the virtual articulator includes a digital model of a mechanical articulator created, for example, from a computer-aided drafting (CAD) file or image data gathered during a laser scan of the

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articulator. Other implementations include a digital model of human jaws created, for example, from 2D or 3D x-ray data, CT scan data, or mechanical measurements of the jaws, or from a combination of these types of data. In many respects, the most useful virtual articulator is the one that simulates the jaws of the patient whose teeth are being treated, which is created from image data or mechanical measurements of the patient's head.

Animation instructions define the movements that the virtual articulator simulates. Like the articulator itself, the animation instructions are derived from a variety of sources. The animation instructions associated with the simulation of a mechanical articulator require little more than a mathematical description of the motion of a mechanical hinge. A virtual articulator simulating the human jaw, on the other hand, requires a more complex set of instructions, based on human anatomical data. One method of building this set of instructions is the derivation of mathematical equations describing the common motions of an ideal human jaw. Another method is through the use of a commercially available jaw-tracking system, which contacts a person's face and provides digital information describing the motion of the lower jaw. X-ray and CT scan data also provide information indicating how the teeth and jaws relate to each other and to the rest of the person's head. Jaw-tracking systems and x-ray and CT scan data are particularly useful in developing an articulator that simulates a particular patient's anatomy.

As the virtual articulator simulates the motion of a patient's teeth, a collision detection process, such as one implementing the oriented bounding box (OBB) algorithm described below, determines whether and how the patient's teeth will collide during the normal course of oral motion. Visual indicators, such as red highlights, appear on a displayed image of the teeth to indicate collision points. The final tooth positions are adjusted, automatically or manually, to avoid collisions detected by the collision detection algorithm.

An automated system for determining final tooth positions and creating the FDDS is described in the above-mentioned U.S. patent application Ser. No. 09/169,036. That application describes a computer-implemented process for generating a set of final positions for a patient's teeth. The process involves creating an ideal model of final tooth positions based on "ideal" tooth arrangements, repositioning the individual teeth in a digital model of the patient's teeth to mimic the ideal model, and modeling the motion of the patient's jaw to perfect the final tooth arrangement.

The display and use of orthodontic-specific information also assists in the determination of final tooth positions. In some implementations, a user can elect to have malocclusion indices, such as Peer Assessment Review (PAR) metrics; shape-based metrics, or distance-based metrics, calculated and displayed with the final tooth positions. If the user is not satisfied with values of the displayed index or indices, the user can adjust the final tooth positions manually until the parameters fall within acceptable ranges. If the tooth positioning system is fully automated, the orthodontic-specific parameters are provided as feedback and used to adjust the final tooth positions until the parameters fall within acceptable ranges.

For human-assisted tooth positioning, the human user also can elect to have positioning tips displayed. Tips are available, for example, to suggest a treatment path for an individual tooth and to warn of excessive forces that might cause patient discomfort or compromise the mechanical integrity of the orthodontic appliance. Tips also are available to

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suggest target positions that best suit the patient's jaw structure and that ensure proper inner digitation and occlusion parameters.

Determining the Steps from the Initial to the Final Position

After the teeth and other components have been placed or removed to produce a model of the final tooth arrangement, it is necessary to generate a treatment plan, as illustrated in FIG. 7. The treatment plan will ultimately produce the series of INTDDS's and FDDS as described previously. To produce these data sets, it is necessary to define or map the movement of selected individual teeth from the initial position to the final position over a series of successive steps. In addition, it may be necessary to add other features to the data sets in order to produce desired features in the treatment appliances. For example, it may be desirable to add wax patches to the image in order to define cavities or recesses for particular purposes, such as to maintain a space between the appliance and particular regions of the teeth or jaw in order to reduce soreness of the gums, avoid periodontal problems, allow for a cap, and the like. Additionally, it will often be necessary to provide a receptacle or aperture intended to accommodate an anchor which is to be placed on a tooth in order to permit the tooth to be manipulated in a manner that requires the anchor, e.g., to be lifted relative to the jaw.

Accounting for Physical Constraints and Additions to the Model

Some methods for manufacturing the tooth repositioning appliances require that the separate, repositioned teeth and other components be unified into a single continuous structure in order to permit manufacturing. In these instances, "wax patches" are used to attach otherwise disconnected components of the INTDDS's. These patches are added to the data set underneath the teeth and above the gum so that they do not effect the geometry of the tooth repositioning appliances. The application software provides for a variety of wax patches to be added to the model, including boxes and spheres with adjustable dimensions. The wax patches that are added are treated by the software as additional pieces of geometry, identical to all other geometries. Thus, the wax patches can be repositioned during the treatment path, as can the teeth and other components. One method of separating the teeth using vertical coring, as described above, removes the need for most of these "wax patches".

In the manufacturing process, adding a wax patch to the graphic model will generate a positive mold that has the same added wax patch geometry. Because the mold is a positive of the teeth and a polymeric appliance is a negative of the teeth, when the appliance is formed over the mold, the appliance will also form around the wax patch that has been added to the mold. When placed in the patient's mouth, the appliance will thus allow for a space between the inner cavity surface of the appliance and the patient's teeth or gums. Additionally, the wax patch may be used to form a recess or aperture within the appliance which engages an anchor placed on the teeth in order to move the tooth in directions which could not otherwise be accomplished.

For some patients an optimal treatment plan requires the interaction of aligners with tooth attachments, such as brackets and anchors, to ensure proper orthodontic correction in a reasonable amount of time. In these situations, the aligners must grip the attachments to ensure that the proper force is exerted on the patient's teeth. For example, an aligner may be designed to grip an anchor planted in the patient's jaw to move the patient's teeth back in the jaw. Likewise, an aligner

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may grip a bracket attached to a patient's tooth to increase the aligner's leverage or grip on the tooth.

The creation of digital attachment models allows the system to model the effects of attachments in analyzing the digital model of a patient's teeth. Each attachment model represents a physical attachment that may be placed in a patient's mouth, generally on a tooth, during the course of treatment. Many attachments, such as conventional brackets, are available in standard shapes and sizes, the models of which can be selected from a library of virtual attachments and added to a patient's tooth model. Other attachments are patient-specific and must be modeled by the user for inclusion in the digital tooth model. The presence of virtual attachments in a patient's tooth model ensures that the aligners fabricated for the patient's treatment plan will accommodate the corresponding physical attachments placed in the patient's mouth during treatment.

The wax patches and virtual attachments described above, and individual components of the tooth model, can be reduced or enlarged in size, which will result in a manufactured appliance having a tighter or looser fit.

Selecting the Intermediate Treatment Stages

Number of Treatment Stages:

The user can change the number of desired treatment stages from the initial to the target states of the teeth. Any component that is not moved is assumed to remain stationary, and thus its final position is assumed to be the same as the initial position (likewise for all intermediate positions, unless one or more key frames are defined for that component).

Key Frames:

The user may also specify "key frames" by selecting an intermediate state and making changes to component position(s). In some embodiments, unless instructed otherwise, the software automatically linearly interpolates between all user-specified positions (including the initial position, all key frame positions, and the target position). For example, if only a final position is defined for a particular component, each subsequent stage after the initial stage will simply show the component an equal linear distance and rotation (specified by a quaternion) closer to the final position. If the user specifies two key frames for that component, the component will "move" linearly from the initial position through different stages to the position defined by the first key frame. It will then move, possibly in a different direction, linearly to the position defined by the second key frame. Finally, it will move, possibly in yet a different direction, linearly to the target position.

These operations may be done independently to each component, so that a key frame for one component will not affect another component, unless the other component is also moved by the user in that key frame. One component may accelerate along a curve between one pair of stages (e.g., stages 3 and 8 in a treatment plan having that many stages), while another moves linearly between another pair of stages (e.g., stages 1 to 5), and then changes direction suddenly and slows down along a linear path to a later stage (e.g., stage 10). This flexibility allows a great deal of freedom in planning a patient's treatment.

In some implementations, non-linear interpolation is used instead of or in addition to linear interpolation to construct a treatment path among key frames. In general, a non-linear path such as a spline curve created to fit among selected points is shorter than a path formed from straight line segments connecting the points. A "treatment path" describes the transformation curve applied to a particular tooth to move the tooth from its initial position to its final

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position. A typical treatment path includes some combination of rotational and translational movement of the corresponding tooth, as described above.

FIGS. 15A and 15B show a linearly interpolated treatment path and a non-linearly interpolated path, respectively, connecting an initial tooth position I to a final tooth position F. The linearly interpolated path consists of straight line segments connecting the initial and final tooth positions as well as the four intermediate tooth positions I_1, I_2, I_3, I_4 . The non-linear interpolated path consists of a curved line fitted among the intermediate tooth positions. The curved path can be formed using a conventional spline-curve fitting algorithm.

FIG. 16 is a flow chart of a computer-implemented process for generating non-linear treatment paths along which a patient's teeth will travel during treatment. The non-linear paths usually are generated automatically by computer program, in some cases with human assistance. The program receives as input the initial and final positions of the patient's teeth and uses this information to select intermediate positions for each tooth to be moved (step 1600). The program then applies a conventional spline curve calculation algorithm to create a spline curve connecting each tooth's initial position to the tooth's final position (step 1602). In many situations, the curve is constrained to follow the shortest path between the intermediate positions. The program then samples each spline curve between the intermediate positions (step 1604) and applies the collision detection algorithm to the samples (step 1606). If any collisions are detected, the program alters the path of at least one tooth in each colliding pair by selecting a new position for one of the intermediate steps (step 1603) and creating a new spline curve (1602). The program then samples the new path (1604) and again applies the collision detection algorithm (1606). The program continues in this manner until no collisions are detected. The routine then stores the paths, e.g., by saving the coordinates of each point in the tooth at each position on the path in an electronic storage device, such as a hard disk (step 1610).

The path-generating program, whether using linear or non-linear interpolation, selects the treatment positions so that the tooth's treatment path has approximately equal lengths between each adjacent pair of treatment steps. The program also avoids treatment positions that force portions of a tooth to move with more than a given maximum velocity. FIG. 15C shows a tooth that is scheduled to move along a first path T1 from an initial position T_{1_1} , to a final position T_{1_3} , through an intermediate position T_{1_2} , which lies closer to the final position T_{1_3} . Another tooth is scheduled to move along a shorter path T2 from an initial position T_{2_1} to a final position T_{2_3} ; through an intermediate position T_{2_2} , which is equidistant from the initial and final positions T_{2_1}, T_{2_3} . In this situation, the program may choose to insert a second intermediate position T_{1_4} along the first path T1 that is approximately equidistant from the initial position T_{1_1} and the intermediate position T_{1_2} and that is separated from these two positions by approximately the same distance that separates the intermediate position T_{1_2} from the final position T_{1_3} .

Altering the first path T1 in this manner ensures that the first tooth will move in steps of equal size. However, altering the first path T1 also introduces an additional treatment step having no counterpart in the second path T2. The program can respond to this situation in a variety of ways, such as by allowing the second tooth to remain stationary during the second treatment step (i.e., as the first tooth moves from one intermediate position T_{1_4} to the other intermediate position

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T_{1_3}) or by altering the second path T2 to include four equidistant treatment positions. The program determines how to respond by applying a set of orthodontic constraints that restrict the movement of the teeth.

Orthodontic constraints that may be applied by the path-generating program include the minimum and maximum distances allowed between adjacent teeth at any given time, the maximum linear or rotational velocity at which a tooth should move, the maximum distance over which a tooth should move between treatment steps, the shapes of the teeth, the characteristics of the tissue and bone surrounding the teeth (e.g., ankylose teeth cannot move at all), and the characteristics of the aligner material (e.g., the maximum distance that the aligner can move a given tooth over a given period of time). For example, the patient's age and jaw bone density may dictate certain "safe limits" beyond which the patient's teeth should not forced to move. In general, a gap between two adjacent, relatively vertical and non-tipped central and lateral teeth should not close by more than about 1 mm every seven weeks. The material properties of the orthodontic appliance also limit the amount by which the appliance can move a tooth. For example, conventional retainer materials usually limit individual tooth movement to approximately 0.5 mm between treatment steps. The constraints have default values that apply unless patient-specific values are calculated or provided by a user. Constraint information is available from a variety of sources, including text books and treating clinicians.

In selecting the intermediate positions for each tooth, the path-generating program invokes the collision detection program to determine whether collisions will occur along the chosen paths. The program also inspects the patient's occlusion at each treatment step along the path to ensure that the teeth align to form an acceptable bite throughout the course of treatment. If collisions or an unacceptable bite will occur, or if a required constraint cannot be satisfied, the program iteratively alters the offending tooth path until all conditions are met. The virtual articulator described above is one tool for testing bite occlusion of the intermediate treatment positions.

As shown in FIG. 17, once the path-generating program has established collision-free paths for each tooth to be moved, the program calls an optimization routine that attempts to make the transformation curve for each tooth between the initial and final positions more linear. The routine begins by sampling each treatment path at points between treatment steps (step 1702), e.g., by placing two sample points between each treatment step, and calculating for each tooth a more linear treatment path that fits among the sample points (step 1704). The routine then applies the collision detection algorithm to determine whether collisions result from the altered paths (step 1706). If so, the routine resamples the altered paths (step 1708) and then constructs for each tooth an alternative path among the samples (step 1710). The routine continues in this manner until no collisions occur (step 1712).

In some embodiments, as alluded to above, the software automatically computes the treatment path, based upon the IDDS and the FDDS. This is accomplished using a path scheduling algorithm which determines the rate at which each component, i.e., each tooth, moves along the path from the initial position to the final position. The path scheduling algorithm determines the treatment path while avoiding "round-tripping," i.e., while avoiding moving a tooth along a distance greater than absolutely necessary to straighten the teeth. Such motion is highly undesirable, and has potential negative effects on the patient.

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One implementation of the path scheduling algorithm attempts first to schedule or stage the movements of the teeth by constraining each tooth to the most linear treatment path between the initial and final positions. The algorithm then resorts to less direct routes to the final positions only if collisions will occur between teeth along the linear paths or if mandatory constraints will be violated. The algorithm applies one of the path-generation processes described above, if necessary, to construct a path for which the intermediate treatment steps do not lie along a linear transformation curve between the initial and final positions. Alternatively, the algorithm schedules treatment paths by drawing upon a database of preferred treatments for exemplary tooth arrangements. This database can be constructed over time by observing various courses of treatment and identifying the treatment plans that prove most successful with each general class of initial tooth arrangements. The path scheduling algorithm can create several alternative paths and present each path graphically to the user. The algorithm provides as output the path selected by the user.

In other implementations, the path scheduling algorithm utilizes a stochastic search technique to find an unobstructed path through a configuration space which describes possible treatment plans. One approach to scheduling motion between two user defined global key frames is described below. Scheduling over a time interval which includes intermediate key frames is accomplished by dividing the time interval into subintervals which do not include intermediate key frames, scheduling each of these intervals independently, and then concatenating the resulting schedules.

Flow chart 120 in FIG. 8A depicts a simplified path scheduling algorithm. As shown in FIG. 8A, first step 122 involves construction of the "configuration space" description. A "configuration," in this context, refers to a given set of positions of all the teeth being considered for movement. Each of these positions may be described in multiple ways. In a common implementation, the positions are described by one affine transformation to specify change in location and one rotational transformation to specify the change in orientation of a tooth from its initial position to its final position. The intermediate positions of each tooth are described by a pair of numbers which specify how far to interpolate the location and orientation between the two endpoints. A "configuration" thus consists of two numbers for each tooth being moved, and the "configuration space" refers to the space of all such number pairs. Thus, the configuration space is a Cartesian space, any location in which can be interpreted as specifying the positions of all teeth.

The affine transformation describing the movement of each tooth from its starting position to its ending position is decomposed into translational and rotational components; these transformations are independently interpolated with scalar parameters which are considered two dimensions of the configuration space. The entire configuration space thus consists of two dimensions per moved tooth, all of which are treated equivalently during the subsequent search.

The configuration space is made of "free space" and "obstructed space." "Free" configurations are those which represent valid, physically realizable positions of teeth, while "obstructed" configurations are those which do not. To determine whether a configuration is free or obstructed, a model is created for the positions of the teeth which the configuration describes. A collision detection algorithm is then applied to determine if any of the geometries describing the tooth surfaces intersect. If there are no obstructions, the

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space is considered free; otherwise it is obstructed. Suitable collision detection algorithms are discussed in more detail below.

At step 124, a "visibility" function $V(s_1, s_2)$ is defined which takes two vectors in the configuration space, " s_1 " and " s_2 ", as input and returns a true or false boolean value. The visibility function returns a true value if and only if a straight line path connecting s_1 and s_2 passes entirely through a free and unobstructed region of the configuration space. One process for carrying out the visibility function is set forth in FIG. 8B. The visibility function is approximately computed by testing the teeth model for interferences at discretely sampled points along the line s_1-s_2 . Techniques such as early termination on failure and choosing the order of sample points by recursively subdividing the interval to be tested, may be used to increase the efficiency of the visibility function.

At step 126 of FIG. 8A, a "children" function $C(s)$ is defined whose input parameter, " s ", is a vector in the configuration space and which returns a set of vectors " s_c " in the configuration space. FIG. 8C depicts a simplified flow chart illustrating the steps followed for computing children function $C(s)$. Each vector within set s_c satisfies the property that $V(s, s_c)$ is true and that each of its components are greater than or equal to the corresponding component of " s ". This implies that any state represented by such a vector is reachable from " s " without encountering any interferences and without performing any motion which is not in the direction prescribed by treatment. Each vector of set " s_c " is created by perturbing each component of " s " by some random, positive amount. The visibility function $V(s, s_c)$ is then computed and " s " added to the set " s_c " if the visibility function returns a true boolean value. Additionally, for each such vector generated, a pointer to its parent " s " is recorded for later use.

After the configuration space has been defined, at step 128, path scheduling is performed between an initial state " s_{init} " and a final state " s_{final} ". FIG. 8D depicts a flow chart for performing step 128 depicted in FIG. 8A. As illustrated in FIG. 8D, at step 128a, a set of states "W" is defined to initially contain only the initial state s_{init} . Next, at step 128b, the visibility function is invoked to determine if $V(s_i, s_{final})$ is true for at least one state s_i in W. If the visibility function returns a false boolean value, at step 128c, the set of states "W" is replaced with the union of $C(s_i)$ for all s_i in W. Steps 128b and 128c are repeated until $V(s_i, s_{final})$ returns a true boolean value for any s_i belonging to W.

At step 128d, for each s_i for which $V(s_i, s_{final})$ is true, an unobstructed path P_i is constructed from s_i to s_{init} by following the parent pointers back to s_{init} . At step 128e, the path from s_{init} to s_{final} is then constructed by concatenating the paths P_i with the final step from s_i to s_{final} . If there are multiple paths from s_{init} to s_{final} , the total length of each path is computed at step 128f. Finally, at step 128g, the path with the shortest length is then chosen as the final path. The length of the chosen path corresponds to the total time and stages required for a treatment plan.

The resulting final path consists of a series of vectors, each of which represents a group of values of the interpolation parameters of the translational and rotational components of the transformations of the moving teeth. Taken together, these constitute a schedule of tooth movement which avoids tooth-to-tooth interferences.

A collision or interference detection algorithm employed in one embodiment is based on the algorithm described in SIGGRAPH article, Stefan Gottschalk et al. (1996): "OBTree: A Hierarchical Structure for Rapid Interference

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Detection." The contents of the SIGGRAPH article are herein incorporated by reference.

The algorithm is centered around a recursive subdivision of the space occupied by an object, which is organized in a binary-tree like fashion. Triangles are used to represent the teeth in the DDS. Each node of the tree is referred to as an oriented bounding box (OBB) and contains a subset of triangles appearing in the node's parent. The children of a parent node contain between them all of the triangle data stored in the parent node.

The bounding box of a node is oriented so it tightly fits around all of the triangles in that node. Leaf nodes in the tree ideally contain a single triangle, but can possibly contain more than one triangle. Detecting collisions between two objects involves determining if the OBB trees of the objects intersect. FIG. 9A sets forth a flow chart depicting a simplified version of a recursive collision test to check if a node "N1" from a first object intersects with node "N2" of a second object. If the OBBs of the root nodes of the trees overlap, the root's children are checked for overlap. The algorithm proceeds in a recursive fashion until the leaf nodes are reached. At this point, a robust triangle intersection routine is used to determine if the triangles at the leaves are involved in a collision.

The collision detection technique described here provides several enhancements to the collision detection algorithm described in the SIGGRAPH article. For example, OBB trees can be built in a lazy fashion to save memory and time. This approach stems from the observation that some parts of the model will never be involved in a collision, and consequently the OBB tree for such parts of the model need not be computed. The OBB trees are expanded by splitting the internal nodes of the tree as necessary during the recursive collision determination algorithm, as depicted in FIG. 9B.

Moreover, the triangles in the model which are not required for collision data may also be specifically excluded from consideration when building an OBB tree. As depicted in FIG. 9C, additional information is provided to the collision algorithm to specify objects in motion. Motion may be viewed at two levels. Objects may be conceptualized as "moving" in a global sense, or they may be conceptualized as "moving" relative to other objects. The additional information improves the time taken for the collision detection by avoiding recomputation of collision information between objects which are at rest relative to each other since the state of the collision between such objects does not change.

FIG. 18 illustrates an alternative collision detection scheme, one which calculates a "collision buffer" oriented along a z-axis 1802 along which two teeth 1804, 1806 lie. The collision buffer is calculated for each treatment step or at each position along a treatment path for which collision detection is required. To create the buffer, an x,y plane 1808 is defined between the teeth 1804, 1806. The plane must be "neutral" with respect to the two teeth. Ideally, the neutral plane is positioned so that it does not intersect either tooth. If intersection with one or both teeth is inevitable, the neutral plane is oriented such that the teeth lie, as much as possible, on opposite sides of the plane. In other words, the neutral plane minimizes the amount of each tooth's surface area that lies on the same side of the plane as the other tooth.

In the plane 1808 is a grid of discrete points, the resolution of which depends upon the required resolution for the collision detection routine. A typical high-resolution collision buffer includes a 400×400 grid; a typical low-resolution buffer includes a 20×20 grid. The z-axis 1802 is defined by a line normal to the plane 1808.

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The relative positions of the teeth 1804, 1806 are determined by calculating, for each of the points in the grid, the linear distance parallel to the z-axis 1802 between the plane 1808 and the nearest surface of each tooth 1804, 1806. For example, at any given grid point (M,N), the plane 1808 and the nearest surface of the rear tooth 1804 are separated by a distance represented by the value $Z_{1(M,N)}$, while the plane 1808 and the nearest surface of the front tooth 1806 are separated by a distance represented by the value $Z_{2(M,N)}$. If the collision buffer is defined such that the plane 1808 lies at z=0 and positive values of z lie toward the back tooth 1804, then the teeth 1804, 1806 collide when $Z_{1(M,N)} \leq Z_{2(M,N)}$ at any grid point (MN) on the plane 1808.

FIG. 19 is a flow chart of a collision detection routine implementing this collision buffer scheme. The routine first receives data from one of the digital data sets indicating the positions of the surfaces of the teeth to be tested (step 1900). The routine then defines the neutral x,y-plane (step 1902) and creates the z-axis normal to the plane (step 1904).

15 The routine then determines for the x,y-position of the first grid point on the plane the linear distance in the z-direction between the plane and the nearest surface of each tooth (step 1906). To detect a collision at that x,y-position, the routine determines whether the z-position of the nearest 20 surface of the rear tooth is less than or equal to the z-position of the nearest surface of the front tooth (step 1908). If so, the routine creates an error message, for display to a user or for feedback to the path-generating program, indicating that a collision will occur (step 1910). The routine then determines 25 whether it has tested all x,y-positions associated with grid points on the plane (step 1912) and, if not, repeats the steps above for each remaining grid point. The collision detection routine is performed for each pair of adjacent teeth in the patient's mouth at each treatment step.

35 Incorporating a Model of an Orthodontic Appliance

Above-mentioned U.S. application Ser. No. 09/169,034, describes an appliance modeling system that implements techniques for modeling the interaction of the patient's teeth with orthodontic appliances, designed to cam-out the patient's treatment plan. Finite element analysis is used to determine the appliance configurations required to move the patient's teeth to the desired final positions along the prescribed treatment paths. In some situations, the appliance modeling system may determine that the desired tooth movement cannot be performed within constraints that are orthodontically acceptable or with an appliance that is manufacturable. The appliance modeling system therefore may determine that a tooth attachment should be added to the model or that the treatment plan should be modified. In 45 these situations, feedback from the appliance modeling system is used to modify the geometric tooth models and the treatment plan accordingly.

Displaying the Treatment Plan Graphically

The system may also incorporate and the user may at any 50 point use a "movie" feature to show an animation of the movement from initial to target states. This is helpful for visualizing overall component movement throughout the treatment process.

As described above, one suitable user interface for component identification is a three dimensional interactive graphical user interface (GUI). A three-dimensional GUI is also advantageous for component manipulation. Such an interface provides the treating professional or user with instant and visual interaction with the digital model components. The three dimensional GUI provides advantages over interfaces that permit only simple low-level commands for directing the computer to manipulate a particular seg-

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ment. In other words, a GUI adapted for manipulation is better in many ways than an interface that accepts directives, for example, only of the sort: "translate this component by 0.1 mm to the right." Such low-level commands are useful for fine-tuning, but, if they were the sole interface, the processes of component manipulation would become a tiresome and time-consuming interaction.

Before or during the manipulation process, one or more tooth components may be augmented with template models of tooth roots. Manipulation of a tooth model augmented with a root template is useful, for example, in situations where impacting of teeth below the gumline is a concern. These template models could, for example, comprise a digitized representation of the patient's teeth x-rays.

The software also allows for adding annotations to the data sets which can comprise text and/or the sequence number of the apparatus. The annotation is added as recessed text (i.e., it is 3-D geometry), so that it will appear on the printed positive model. If the annotation can be placed on a part of the mouth that will be covered by a repositioning appliance, but is unimportant for the tooth motion, the annotation may appear on the delivered repositioning appliance(s).

The above-described component identification and component manipulation software is designed to operate at a sophistication commensurate with the operator's training level. For example, the component manipulation software can assist a computer operator, lacking orthodontic training, by providing feedback regarding permissible and forbidden manipulations of the teeth. On the other hand, an orthodontist, having greater skill in intraoral physiology and teeth-moving dynamics, can simply use the component identification and manipulation software as a tool and disable or otherwise ignore the advice.

FIG. 20 is a screen shot of the graphical user interface 2000 associated with a client viewer application through which a treating clinician is able to view a patient's treatment plan and alter or comment on the plan. The client viewer application is implemented in a computer program installed locally on a client computer at the clinician's site. The viewer program downloads a data file from a remote host, such as a, file transfer protocol (FTP) server maintained by the treatment plan designer, which can be accessed either through direct connection or through a computer network, such as the World Wide Web. The viewer program uses the downloaded file to present the treatment plan graphically to the clinician. The viewer program also can be used by the treatment plan designer at the host site to view images of a patient's teeth.

The data downloaded by the viewer program contains a fixed subset of key treatment positions, including the IDDS and the FDSS, that define the treatment plan for the patient's teeth. The viewer program renders the IDDS or the FDSS to display an image of the patient's teeth at the initial and final positions. The viewer program can display an image of the teeth at their initial positions (initial image 2002) and the final tooth positions (final image 2004) concurrently.

Because the data file contains a large amount of data, the download software in the remote host employs a "level-of-detail" technique to organize the download into data groups with progressively increasing levels of detail, as described below. The viewer program uses knowledge of orthodontic relevance to render less important areas of the image at a lower quality than it renders the more important areas. Use of these techniques reduces the time required to generate a

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single rendered image of the tooth models and the time required to display a rendered image on the screen after the download has begun.

FIGS. 21A and 21B illustrate the use of the "level-of-detail" technique by the download software in the remote host. The software transfers the data in several groups, each of which adds detail incrementally for the rendered image of the teeth. The first group typically includes just enough data to render a rough polygon representation of the patient's teeth. For example, if a tooth is treated as a cube having six faces, the tooth can be rendered quickly as a diamond 2100 having six points 2102a-f, one lying in each face of the cube (FIG. 21A). The download software begins the download by delivering a few points for each tooth, which the interface program uses to render polygon representations of the teeth immediately.

The download software then delivers a second data group that adds additional detail to the rendered images of the teeth. This group typically adds points that allow a spheroid representation 2106 of the teeth (FIG. 21B). As the download continues, the software delivers additional groups of data, each adding a level of detail to the rendered image of the teeth, until the teeth are fully rendered.

The download software also improves download and rendering speed by identifying and, withholding data that is not critical to forming a rendered image of the teeth. This includes data for tooth surfaces obscured by other teeth or by tissue. The software applies rules based on common orthodontic structure to determine which data is downloaded and which is withheld. Withholding data in this manner reduces the size of the downloaded file and therefore reduces the number of data points that the interface program must take into account when rendering the initial and final images.

The viewer program also improves rendering speed by reducing the amount of data rendered. Like the download software, the viewer program applies rules of orthodontic relevance to determine which areas of the image can be rendered at lower quality. For example, the treating clinician usually does not want to view gum tissue in detail, so the viewer program renders the gums at low resolution as smooth surfaces, ignoring data that preserves the texture of the gums. Typically, the viewer program renders the less important areas at lower resolution before rendering the more important areas at higher resolution. The clinician can request high resolution rendering of the entire image.

As shown in FIG. 20 and discussed above, the viewer program displays an initial image 2002 of the teeth and, if requested by the clinician, a final image 2004 of the teeth as they will appear after treatment. The clinician can rotate the images in three dimensions to view the various tooth surfaces, and the clinician can snap the image to any of several predefined viewing angles. These viewing angles include the standard front, back, top, bottom and side views, as well as orthodontic-specific viewing angles, such as the lingual, buccal, facial, occlusal, and incisal views.

The viewer program also includes an animation routine that provides a series of images showing the positions of the teeth at each intermediate step along the treatment path. The clinician controls the animation routine through a VCR metaphor, which provides control buttons similar to those on a conventional video cassette recorder. In particular, the VCR metaphor includes a "play" button 2006 that, when selected, causes the animation routine to step through all of the images along the treatment path. A slide bar 2008 moves horizontally a predetermined distance with each successive image, displayed. Each position of the slide bar 2008 and

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each image in the series corresponds to one of the intermediate treatment steps described above.

The VCR metaphor also includes a "step forward" button 2010 and a "step back" button 2012, which allow the clinician to step forward or backward through the series of images, one key frame or treatment step at a time, as well as a "fast forward" button 2014 and a "fast back" button 2016, which allow the clinician to jump immediately to the final image 2004 or initial image 2002, respectively. The clinician also can step immediately to any image in the series by positioning the slide bar 2008 at the appropriate location.

As described above, the viewer program receives a fixed subset of key positions, including the IDDS and the FDDS, from the remote host. From this data, the animation routine derives the transformation curves required to display the teeth at the intermediate treatment steps, using any of a variety of mathematical techniques. One technique is by invoking the path-generation program described above. In this situation, the viewer program includes the path-generation program code. The animation routine invokes this code either when the downloaded key positions are first received or when the user invokes the animation routine.

The viewer program allows the clinician to alter the rendered image by manipulating the image graphically. For example, the clinician can reposition an individual tooth by using a mouse to click and drag or rotate the tooth to a desired position. In some implementations, repositioning an individual tooth alters only the rendered image; in other implementations, repositioning a tooth in this manner modifies the underlying data set. In the latter situation, the viewer program performs collision detection to determine whether the attempted alteration is valid and, if not, notifies the clinician immediately. Alternatively, the viewer program modifies the underlying data set and then uploads the altered data set to the remote host, which performs the collision detection algorithm. The clinician also can provide textual feedback to the remote host through a dialog box 2018 in the interface display 2000. Text entered into the dialog box 2018 is stored as a text object and later uploaded to the remote host or, alternatively, is delivered to the remote host immediately via an existing connection.

The viewer program optionally allows the clinician to isolate the image of a particular tooth and view the tooth apart from the other teeth. The clinician also can change the color of an individual tooth or group of teeth in a single rendered image or across the series of images. These features give the clinician a better understanding of the behavior of individual teeth during the course of treatment.

Another feature of the viewer program allows the clinician to receive information about a specific tooth or a specific part of the model upon command, e.g., by selecting the area of interest with a mouse. The types of information available include tooth type, distance between adjacent teeth, and forces (magnitudes and directions) exerted on the teeth by the aligner or by other teeth. Finite element analysis techniques are used to calculate the forces exerted on the teeth. The clinician also can request graphical displays of certain information, such as a plot of the forces exerted on a tooth throughout the course of treatment or a chart showing the movements that a tooth will make between steps on the treatment path. The viewer program also optionally includes "virtual calipers," a graphical tool that allows the clinician to select two points on the rendered image and receive a display indicating the distance between the points.

Fabricating the Aligners

Once the intermediate and final data sets have been created, the appliances may be fabricated as illustrated in

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FIG. 10. Common fabrication methods employ a rapid prototyping device 200 such as a stereolithography machine. A particularly suitable rapid prototyping machine is Model SLA-250/50 available from 3D System, Valencia, Calif. The rapid prototyping machine 200 selectively hardens a liquid or other non-hardened resin into a three-dimensional structure which can be separated from the remaining non-hardened resin, washed, and used either directly as the appliance or indirectly as a mold for producing the appliance. The prototyping machine 200 receives the individual digital data sets and produces one structure corresponding to each of the desired appliances. Generally, because the rapid prototyping machine 200 may utilize a resin having non-optimum mechanical properties and which may not be generally acceptable for patient use, the prototyping machine typically is used to produce molds which are, in effect, positive tooth models of each successive stage of the treatment. After the positive models are prepared, a conventional pressure or vacuum molding machine is used to produce the appliances from a more suitable material, such as 0.03 inch thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. 55902. Suitable pressure molding equipment is available under the trade name BIOSTAR from Great Lakes Orthodontics, Ltd., Tonawanda, N.Y. 14150. The molding machine 250 produces each of the appliances directly from the positive tooth model and the desired material. Suitable vacuum molding machines are available from Raintree Essix, Inc.

After production, the appliances can be supplied to the treating professional all at one time. The appliances are marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

Because a patient's teeth may respond differently than originally expected, the treating clinician may wish to evaluate the patient's progress during the course of treatment. The system can also do this automatically, starting from the newly-measured in-course dentition. If the patient's teeth do not progress as planned, the clinician can revise the treatment plan as necessary to bring the patient's treatment back on course or to design an alternative treatment plan. The clinician may provide comments, oral or written, for use in revising the treatment plan. The clinician also can form another set of plaster castings of the patient's teeth for digital imaging and manipulation. The clinician may wish to limit initial aligner production to only a few aligners, delaying production on subsequent aligners until the patient's progress has been evaluated.

FIG. 11 is a simplified block diagram of a data processing system 300 that may be used to develop orthodontic treatment plans. The data processing system 300 typically includes at least one processor 302 which communicates with a number of peripheral devices via bus subsystem 304. These peripheral devices typically include a storage subsystem 306 (memory subsystem 308 and file storage subsystem 314), a set of user interface input and output devices 318, and an interface to outside networks 316, including the public switched telephone network. This interface is shown schematically as "Modems and Network Interface" block 316, and is coupled to corresponding interface devices in other data processing systems via communication network

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interface 324. Data processing system 300 could be a terminal or a low-end personal computer or a high-end personal computer, workstation or mainframe.

The user interface input devices typically include a keyboard and may further include a pointing device and a scanner. The pointing device may be an indirect pointing device such as a mouse, trackball, touchpad, or graphics tablet, or a direct pointing device such as a touchscreen incorporated into the display, or a three dimensional pointing device, such as the gyroscopic pointing device described in U.S. Pat. No. 5,440,326, other types of user interface input devices, such as voice recognition systems, can also be used.

User interface output devices typically include a printer and a display subsystem, which includes a display controller and a display device coupled to the controller. The display device may be a cathode ray tube (CRT), a flat-panel device such as a liquid crystal display (LCD), or a projection device. The display subsystem may also provide non-visual display such as audio output.

Storage subsystem 306 maintains the basic required programming and data constructs. The program modules discussed above are typically stored in storage subsystem 306. Storage subsystem 306 typically comprises memory subsystem 308 and file storage subsystem 314.

Memory subsystem 308 typically includes a number of memories including a main random access memory (RAM) 310 for storage of instructions and data during program execution and a read only memory (ROM) 312 in which fixed instructions are stored. In the case of Macintosh-compatible personal computers the ROM would include portions of the operating system; in the case of IBM-compatible personal computers, this would include the BIOS (basic input/output system).

File storage subsystem 314 provides persistent (non-volatile) storage for program and data files, and typically includes at least one hard disk drive and at least one floppy disk drive (with associated removable media). There may also be other devices such as a CD-ROM drive and optical drives (all with their associated removable media). Additionally, the system may include drives of the type with removable media cartridges. The removable media cartridges may, for example be hard disk cartridges, such as those marketed by Syquest and others, and flexible disk cartridges, such as those marketed by Iomega. One or more of the drives may be located at a remote location, such as in a server on a local area network or at a site on the Internet's World Wide Web.

In this context, the term "bus subsystem" is used generally so as to include any mechanism for letting the various components and subsystems communicate with each other as intended. With the exception of the input devices and the display, the other components need not be at the same physical location. Thus, for example, portions of the file storage system could be connected via various local-area or wide-area network media, including telephone lines. Similarly, the input devices and display need not be at the same location as the processor, although it is anticipated that personal computers and workstations typically will be used.

Bus subsystem 304 is shown schematically as a single bus, but a typical system has a number of buses such as a local bus and one or more expansion buses (e.g., ADB, SCSI, ISA, EISA, MICA, NuBus, or PCI), as well as serial and parallel ports. Network connections are usually established through a device such as a network adapter on one of these expansion buses or a modem on a serial port. The client computer may be a desktop system or a portable system.

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Scanner 320 is responsible for scanning casts of the patient's teeth obtained either from the patient or from an orthodontist and providing the scanned digital data set information to data processing system 300 for further processing. In a distributed environment, scanner 320 may be located at a remote location and communicate scanned digital data set information to data processing system 300 via network interface 324.

Fabrication machine 322 fabricates dental appliances based on intermediate and final data set information received from data processing system 300. In a distributed environment, fabrication machine 322 may be located at a remote location and receive data set information from data processing system 300 via network interface 324.

The invention has been described in terms of particular embodiments. Other embodiments are within the scope of the following claims. For example, the three-dimensional scanning techniques described above may be used to analyze material characteristics, such as shrinkage and expansion, of the materials that form the tooth castings and the aligners. Also, the 3D tooth models and the graphical interface described above may be used to assist clinicians that treat patients with conventional braces or other conventional orthodontic appliances, in which case the constraints applied to tooth movement would be modified accordingly. Moreover, the tooth models may be posted on a hypertext transfer protocol (http) web site for limited access by the corresponding patients and treating clinicians.

Many alterations and modifications may be made by those of ordinary skill in this art, without departing from the spirit and scope of this invention. The illustrated embodiments have been shown only for purposes of clarity and the examples should not be taken as limiting the invention as defined in the following claims. Which claims are intended to include all equivalents, whether now or later devised.

What is claimed is:

1. A computer-implemented method for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the method comprising:
receiving an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof; generating a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions; and
generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,
wherein the plurality of successive appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to reposition the teeth.
2. The method of claim 1, wherein receiving the initial digital data set comprises receiving data obtained by scanning a physical model of the patient's teeth.
3. The method of claim 2, further comprising scanning the physical model with a destructive scanning system.
4. The method of claim 3, further comprising scanning the physical model with a laser scanning system before scanning the model with the destructive scanning system.
5. The method of claim 2, further comprising scanning physical models of the patient's upper and lower teeth in occlusion.

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6. The method of claim 5, wherein scanning the physical models of the patient's upper and lower teeth comprises scanning the physical models with a laser scanning system.

7. The method of claim 2, wherein receiving the initial data set includes receiving image data obtained directly by imaging the patient's teeth.

8. The method of claim 7, wherein the image data is digital.

9. The method of claim 7, wherein the image data includes at least one of the following: 2D x-ray data, 3D x-ray data, CT scan data, and MRI data.

10. The method of claim 2, further comprising analyzing the data obtained by scanning the physical model to determine physical characteristics of a material used in the model.

11. The method of claim 1, wherein receiving the initial digital data set comprises receiving data obtained by scanning two physical models of the patient's teeth,

one representing a positive impression of the teeth and one representing a negative impression of the teeth.

12. The method of claim 11, further comprising scanning the positive impression and the negative impression while interlocked with each other.

13. The method of claim 1, wherein the initial digital data set includes volume image data of the patient's teeth and the method includes converting the volume image data into a 3D geometric model of the tooth surfaces.

14. The method of claim 13, wherein converting the volume image data comprises detecting volume elements in the image data between which a large transition in image value occurs.

15. The method of claim 1, further comprising applying a set of predefined rules to segment the initial data set into 3D models of individual dentition components of the patient's mouth.

16. The method of claim 15, further comprising deriving the rules from a database of information indicating how a typical data set is segmented into individual tooth models.

17. The method of claim 15, wherein the rules include information about the cusp structure of typical teeth.

18. The method of claim 15, wherein one of the dentition components comprises at least a portion of an individual tooth.

19. The method of claim 15, wherein one of the dentition components comprises gum in the patient's mouth.

20. The method of claim 15, wherein applying the set of predetermined rules comprises applying a rule for recognizing noise in a tooth cast from which the initial data set is derived.

21. The method of claim 1, further comprising applying rules of orthodontic relevance to reduce the amount of data in the initial data set associated with less important orthodontic features.

22. The method of claim 1, further comprising modifying the initial data set to include data representing a hidden tooth surface.

23. The method of claim 22, wherein the hidden tooth surfaces include tooth roots.

24. The method of claim 22, wherein the data representing the hidden tooth surfaces comprises image data representing the hidden surfaces of the patient's teeth.

25. The method of claim 24, wherein the image data comprises at least one of the following: X-ray data, CT scan data, MRI data.

26. The method of claim 22, wherein the data representing the hidden tooth surfaces comprises data representing the hidden surfaces of typical teeth.

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27. The method of claim 22, further comprising extrapolating visible surfaces of the patient's teeth to derive the data representing the hidden tooth surfaces.

28. The method of claim 22, further comprising: receiving image data containing an image of the patient's teeth; analyzing the image data to identify a particular feature of at least one of the patient's teeth; and using the identified feature to guide the inclusion of the hidden tooth surface.

29. The method of claim 28, wherein the image data is digital.

30. The method of claim 28, wherein the image data comprises at least one of the following: 2D x-ray data, 3D x-ray data, CT scan data, and MRI data.

31. The method of claim 1, further comprising receiving information indicating whether the patient's teeth are moving as planned and, if not, using the information to revise the set of intermediate positions.

32. The method of claim 1, wherein generating the set of intermediate positions comprises generating more than one candidate set of intermediate position for each tooth and providing a graphical display of each candidate set to a human user for selection.

33. The method of claim 1, further comprising applying a set of rules to detect any collisions that will occur between teeth as the patient's teeth move toward the set of final positions.

34. The method of claim 33, wherein detecting collisions comprises calculating distances between a first tooth and a second tooth by:

establishing a neutral projection plane between the first tooth and the second tooth,
establishing a z-axis that is normal to the plane and that has a positive direction and a negative direction from each of a set of base points on the projection plane, computing a pair of signed distances comprising a first signed distance to the first tooth and a second signed distance to the second tooth, the signed distances being measured on a line through the base points and parallel to the z-axis, and determining that a collision occurs if any of the pair of signed distances indicates a collision.

35. The method of claim 34, wherein the positive direction for the first distance is opposite the positive direction for the second distance and a collision is detected if the sum of any pair of signed distances is less than or equal to zero.

36. The method of claim 1, further comprising applying a set of rules to detect any improper bite occlusions that will occur as the patient's teeth move toward the set of final positions.

37. The method of claim 36, further comprising calculating a value for a malocclusion index and displaying the value to a human user.

38. The method of claim 1, wherein generating the set of intermediate positions includes receiving data indicating restraints on movement of the patient's teeth and applying the data to generate the intermediate positions.

39. The method of claim 1, wherein generating the set of intermediate positions includes determining the minimum amount of transformation required to move each tooth from the initial position toward the final position and creating the intermediate positions to require the minimum amount of movement.

40. The method of claim 39, wherein each set of intermediate positions is created to require, in addition to the

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minimum amount of movement, any movement that is needed to satisfy an orthodontic restraint that applies to the corresponding tooth.

41. The method of claim 1, wherein generating the set of intermediate positions includes generating intermediate positions for at least one tooth between which the tooth undergoes translational movements of equal sizes.

42. The method of claim 1, further comprising rendering a representation of the teeth at the set of positions corresponding to a selected data set.

43. The method of claim 42, further comprising using only a portion of the data in the selected data set to render the graphical representation of the teeth.

44. The method of claim 42, further comprising applying level-of-detail compression to the data set to render the graphical representation of the teeth.

45. The method of claim 42, further comprising receiving an instruction from a human user to modify the graphical representation of the teeth and modifying the graphical representation in response to the instruction.

46. The method of claim 45, further comprising modifying the selected data set in response to the instruction from the user.

47. The method of claim 42, further comprising allowing a human user to select a tooth in the graphical representation and, in response, displaying information about the tooth.

48. The method of claim 47, wherein the information relates to the forces that the tooth will experience while moving toward the set of final positions.

49. The method of claim 47, wherein the information indicates a linear distance between the tooth and another tooth selected in the graphical representation.

50. The method of claim 42, wherein rendering the graphical representation comprises rendering the teeth at a selected one of multiple viewing orthodontic-specific viewing angles.

51. The method of claim 42, further comprising providing a user interface through which a human user can provide text-based comments after viewing the graphical representation of the patient's teeth.

52. The method of claim 42, wherein rendering the graphical representation comprises downloading data to a remote computer.

53. The method of claim 42, further comprising receiving an input signal from a 3D input device controlled by a human user and using the input signal to alter the orientation of the teeth in the graphical representation.

54. The method of claim 53, wherein the 3D input device comprises a gyroscopic pointing device.

55. The method of claim 42, further comprising subsequently rendering a graphical representation of the teeth at the set of positions corresponding to another of the data sets to illustrate how the patient's teeth will move during treatment.

56. The method of claim 55, wherein the graphical representation includes a three dimensional representation of the teeth.

57. The method of claim 42, further comprising: receiving data indicating two positions in the graphical representation that a user has selected with a pointing device; calculating the distance between the two points; and displaying the distance in the graphical representation.

58. The method of claim 42, wherein the representation includes a three-dimensional (3D) graphical representation of the teeth.

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59. The method of claim 1, further comprising providing a user interface with an input component that allows a human user to control an animation of the movement of the teeth.

60. The method of claim 59, wherein the input components allow the user to take any of the following actions: view the animation at a normal frame rate, step through the animation one frame at a time, select a particular frame in the animation for viewing, and stop the animation.

61. The method of claim 59, wherein the user interface includes a graphical user interface.

62. The method of claim 1, further comprising delivering data identifying the intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final positions.

63. The method of claim 62, further comprising including in the data a digital model of an orthodontic attachment that the appliance must accommodate.

64. The method of claim 63, wherein the digital model represents an attachment to be placed on one of the patient's teeth.

65. The method of claim 63, wherein the digital model represents an anchor to be placed in the patient's mouth and against which the appliance must pull.

66. The method of claim 62, further comprising receiving data indicating material properties of the appliance to be fabricated and using the data to generate the set of intermediate positions.

67. The method of claim 1, further comprising generating a final data set representing the teeth at the final positions.

68. The method of claim 1, further comprising generating a series of orthodontic devices for repositioning the patient's teeth from the initial positions to the final positions.

69. The method of claim 68, further comprising: using the appliances to treat the patient's teeth; receiving an in-course digital data set representing actual positions of the patient's teeth after treatment has begun; and displaying a graphical representation of the patient's teeth at the actual positions.

70. The method of claim 1, further comprising generating treatment paths among the intermediate positions along which the teeth will move from the initial positions toward the final positions.

71. The method of claim 1, further comprising generating an alternative set of intermediate treatment positions.

72. The method of claim 71, further comprising displaying at least two different sets of intermediate treatment positions to a user and allowing the user to select one of the sets for use in treating the patient's teeth.

73. The method of claim 1, further comprising generating, for each tooth at each tooth position, a transformation representing a translational position of the tooth and a rotational position of the tooth with respect to an origin.

74. The method of claim 1, wherein generating the intermediate positions comprises representing the teeth in a configuration space.

75. The method of claim 1, further comprising generating a renderable model of the patient's teeth at the final positions.

76. The method of claim 75, further comprising making the renderable model available on a computer accessible by the treating clinician.

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77. The method of claim 76, further comprising generating a graphical representation of the patient's teeth at the final positions when the clinician accesses the renderable model.

78. The method of claim 75, further comprising making the renderable model available on a computer accessible by the patient.

79. The method of claim 78, further comprising generating a graphical representation of the patient's teeth at the final positions when the patient accesses the renderable model.

80. The method of claim 1, wherein generating the intermediate treatment positions comprises receiving information about a material property of a device that will be used to treat the patient's teeth and deriving from the information a constraint on the movement of at least one of the teeth.

81. A computer program, residing on a tangible storage medium, for use in creating a treatment plan to reposition a patient's teeth from a set of initial tooth positions to a set of final tooth positions, the program comprising executable instructions operable to cause a computer to:

receive an initial digital data set representing the teeth at the initial positions, wherein receiving the initial digital data set comprises receiving data obtained by scanning the patient's teeth or a physical model thereof; generate a set of intermediate positions toward which the teeth will move while moving from the initial positions toward the final positions, as to allow

generating a plurality of successive appliances having cavities and wherein the cavities of successive appliances have different geometries shaped to receive and reposition teeth from the initial positions toward the final positions,

wherein the plurality of appliances is generated at a stage of treatment prior to the patient wearing any appliance of said plurality so as to achieve repositioning of the teeth.

82. The program of claim 81, wherein the initial digital data set includes data obtained by scanning a physical model of the patient's teeth.

83. The program of claim 81, wherein the initial digital data set includes data obtained by scanning a positive impression and a negative impression of the patient's teeth interlocked together.

84. The program of claim 81, wherein the initial digital data set includes volume image data of the patient's teeth and the computer converts the volume image data into a 3D geometric model of the tooth surfaces by detecting volume elements in the image data between which a large transition in image value occurs.

85. The program of claim 81, wherein the computer applies a set of predefined rules to segment the initial data set into 3D models of the individual teeth.

86. The program of claim 81, wherein the computer modifies the initial digital data set to include data representing hidden tooth surfaces.

87. The program of claim 81, wherein the computer applies a set of rules to detect any collisions that will occur as the patient's teeth move toward the final positions.

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88. The program of claim 87, the computer detects collisions by calculating distances between a first tooth and a second tooth by:

establishing a neutral projection plane between the first tooth and the second tooth,
establishing a z-axis that is normal to the plane and that has a positive direction and a negative direction from each of a set of base points on the projection plane, computing a pair of signed distances comprising a first signed distance to the first tooth and a second signed distance to the second tooth, the signed distances being measured on a line through the base points and parallel to the z-axis, and

determining that a collision occurs if any of the pair of signed distances indicates a collision.

89. The method of claim 88, wherein the positive direction for the first distance is opposite the positive direction for the second distance and a collision is detected if the sum of any pair of signed distances is less than or equal to zero.

90. The program of claim 81, wherein the computer applies a set of rules to detect any improper bite occlusions that will occur as the patient's teeth move toward the final positions.

91. The program of claim 81, wherein the computer renders a 3D graphical representation of the teeth at the positions corresponding to a selected data set.

92. The program of claim 91, wherein the computer animates the graphical representation of the teeth to provide a visual display of the movement of the teeth toward the final positions.

93. The program of claim 81, wherein the computer applies level-of-detail compression to the selected data set to render the graphical representation of the teeth.

94. The program of claim 81, wherein the computer receives an instruction from a human user to modify the graphical representation of the teeth and, in response to the instruction, modifies the graphical representation and the selected data set.

95. The program of claim 81, wherein the computer delivers data identifying the intermediate treatment positions to an appliance fabrication system for use in fabricating at least one orthodontic appliance structured to move the patient's teeth toward the final positions.

96. The program of claim 95, wherein the computer includes in the data a digital model of an orthodontic attachment that the appliance must accommodate.

97. The program of claim 81, wherein the computer generates a final data set representing the teeth at the final positions.

98. The program of claim 81, wherein the computer generates data for use in creating a series of orthodontic devices for repositioning the patient's teeth from the initial positions to the final positions.

99. The program of claim 81, wherein the computer generates treatment paths among the intermediate positions along which the teeth will move from the initial positions toward the final positions.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,134,874 B2
APPLICATION NO. : 10/718779
DATED : November 14, 2006
INVENTOR(S) : Muhammad Chishti et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

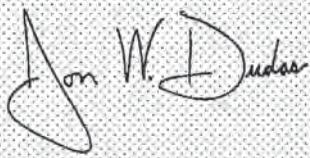
On the title page item (63), delete "Continuation of application No. 09/686,190, filed on Oct. 10, 2000, now abandoned, which is a continuation of application No. 09/169,276, filed on Oct. 8, 1998, now abandoned, which is a continuation-in-part of application No. PCT/US98/12681, filed on Jun. 19, 1998."

and insert -- This application is a continuation of U.S. application Ser. No. 09/686,190, filed Oct. 10, 2000, (now abandoned), which was a continuation of U.S. application Ser. No. 09/169,276, filed Oct. 8, 1998, (now abandoned), which is a continuation-in-part of PCT Application No. PCT/US98/12861, filed Jun. 19, 1998, which claims priority from U.S. patent application Ser. No. 08/947,080, filed Oct. 8, 1997 (now U.S. Pat. No. 5,975,893), which claims priority from U.S. Provisional Application No. 60/050,342, filed on Jun. 20, 1997, the full disclosures of which are incorporated in this application by reference. --

Column 1, lines 12-13, please delete "PCT/US/99/12691" and insert
-- PCT/US98/12861 --.

Signed and Sealed this

First Day of May, 2007



JON W. DUDAS

Director of the United States Patent and Trademark Office

A311

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January 27, 2012

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
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U.S. PATENT: 8,070,487

ISSUE DATE: December 06, 2011

By Authority of the
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Certifying Officer



A3112



US008070487B2

(12) **United States Patent**
Chishti et al.

(10) Patent No.: **US 8,070,487 B2**
(45) Date of Patent: ***Dec. 6, 2011**

(54) **SYSTEM AND METHOD FOR POSITIONING TEETH**

(75) Inventors: Muhammad Chishti, Washington, DC (US); Andrew Beers, Menlo Park, CA (US)

(73) Assignee: Align Technology, Inc., San Jose, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 80 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **11/981,680**

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(63) Continuation of application No. 10/788,510, filed on Feb. 27, 2004, now Pat. No. 7,331,783, which is a continuation of application No. 10/133,155, filed on Apr. 26, 2002, now Pat. No. 6,786,721, which is a continuation of application No. 09/169,036, filed on Oct. 8, 1998, now Pat. No. 6,450,807, which is a continuation-in-part of application No. PCT/US98/12861, filed on Jun. 19, 1998.

(60) Provisional application No. 60/050,342, filed on Jun. 20, 1997.

(51) **Int. Cl.**
A61C 3/00 (2006.01)

(52) **U.S. Cl.** 433/24
(58) **Field of Classification Search** 433/6, 24,
433/213; 700/98, 95, 97

See application file for complete search history.

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Primary Examiner — Todd Manahan

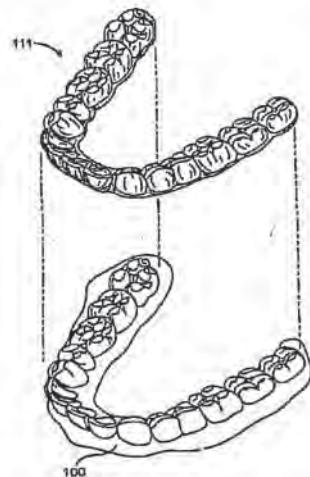
Assistant Examiner — Matthew Nelson

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(57) **ABSTRACT**

Methods and apparatus fit a set of upper and lower teeth in a masticatory system by generating a computer representation of the masticatory system and computing an occlusion based on interactions in the computer representation of the masticatory system.

17 Claims, 6 Drawing Sheets



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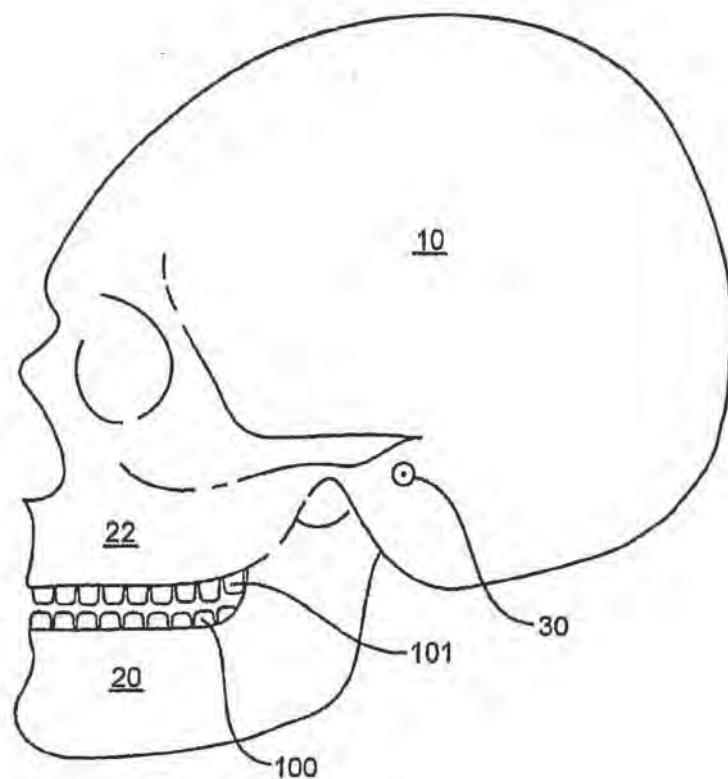


FIG. 1

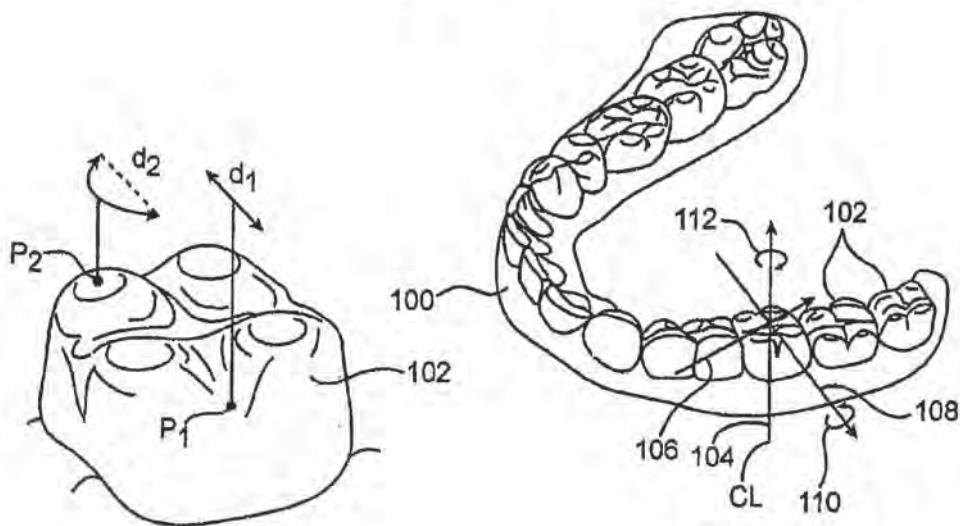


FIG. 2B

FIG. 2A

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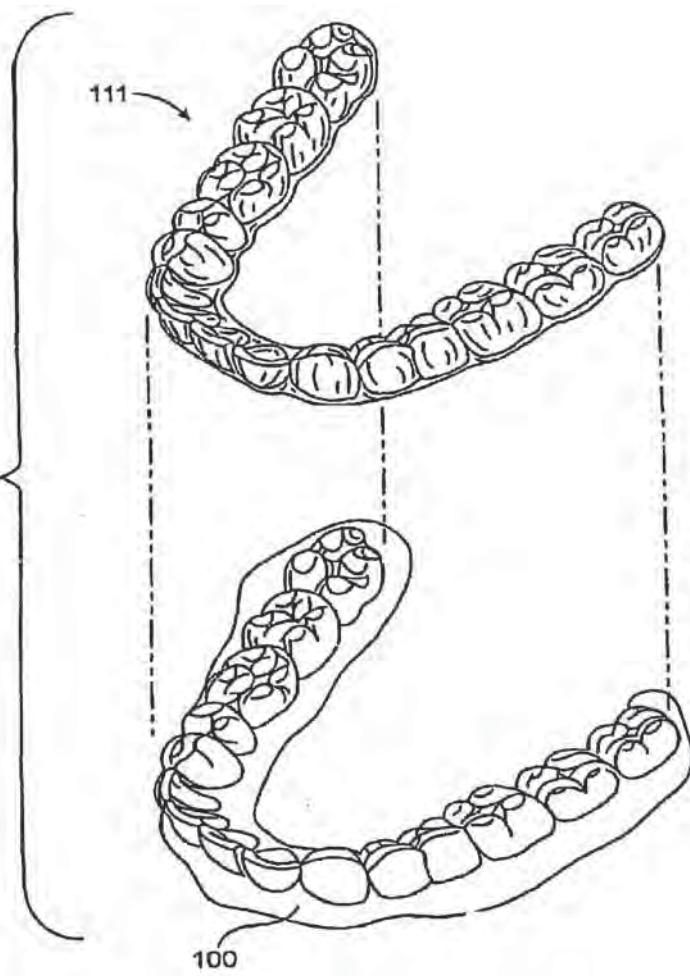
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FIG. 2C



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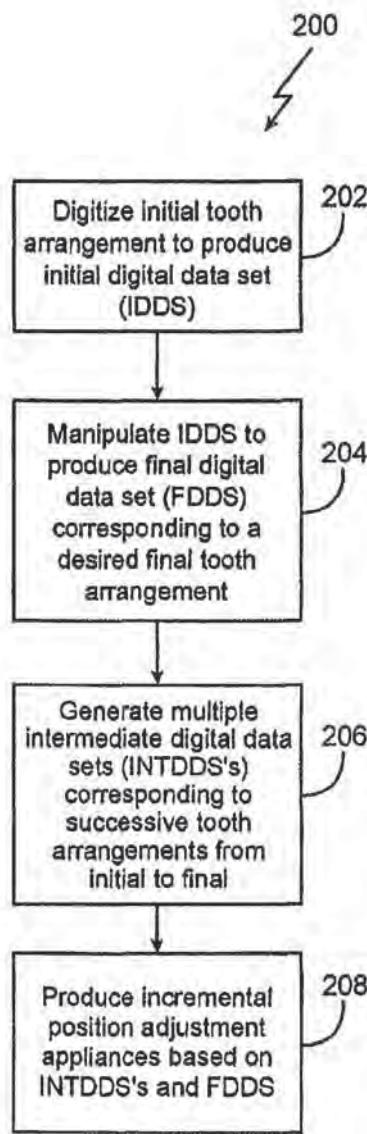


FIG. 3

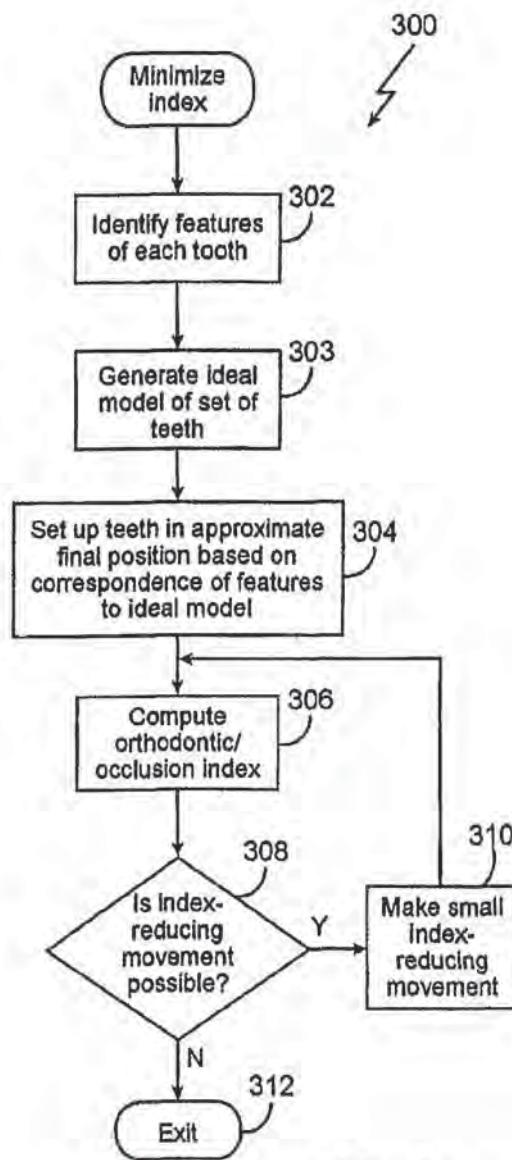


FIG. 4

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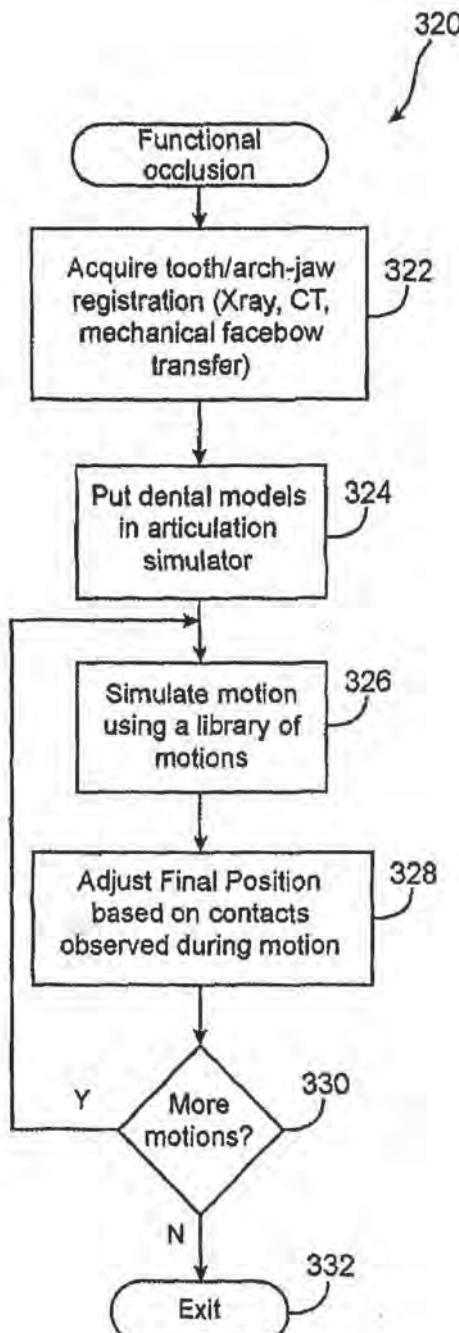


FIG. 5

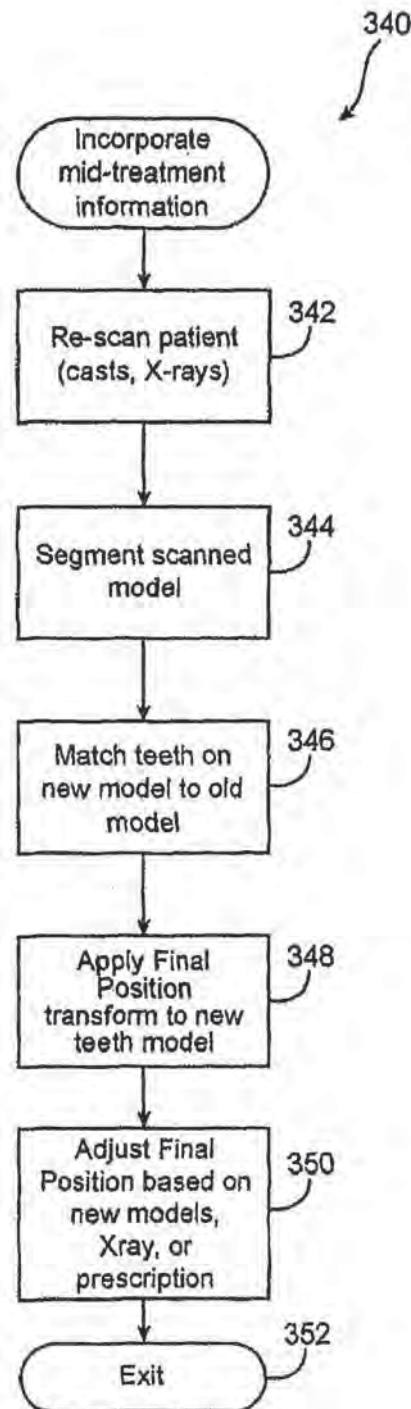


FIG. 6

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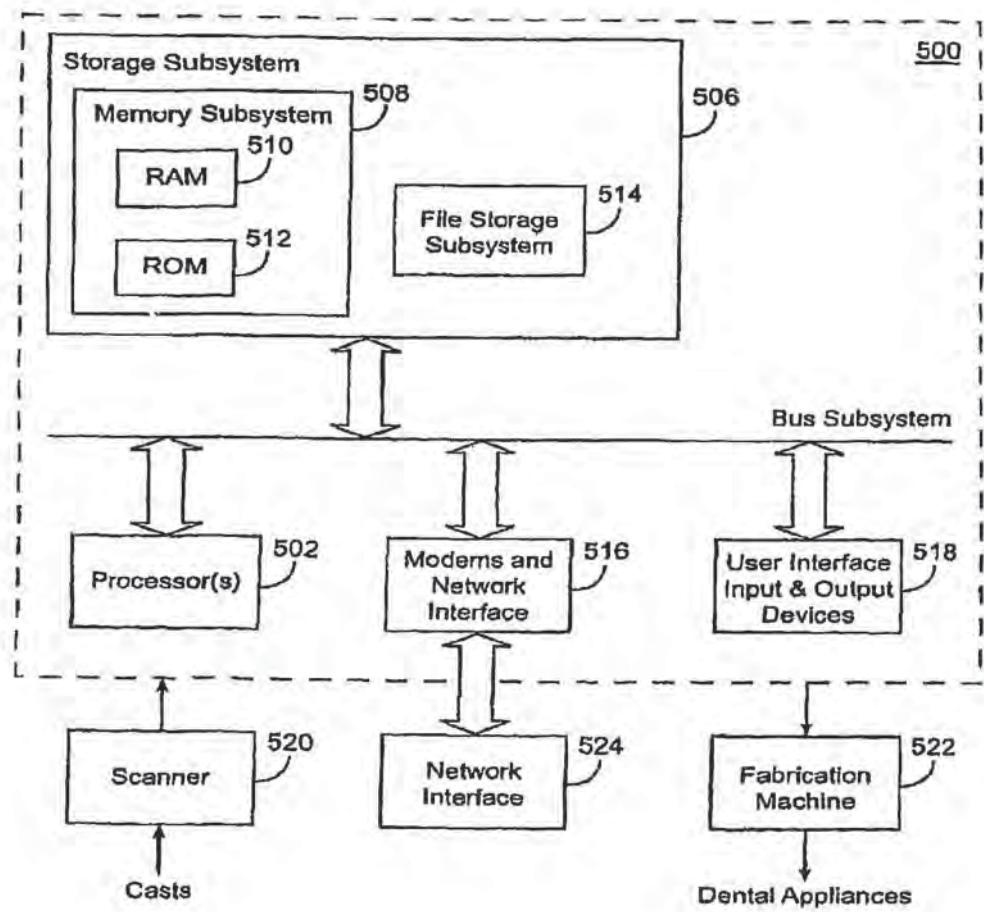


FIG. 7

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Provide a static occlusion determined from a computer representation of the masticatory system

Model an ideal set of teeth

Automatically apply the ideal set of teeth to the computer representation of the masticatory system of the patient

Optimize the position of the patient's teeth to fit the ideal set of teeth

FIG. 8

A3123

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1

SYSTEM AND METHOD FOR POSITIONING TEETH**CROSS-REFERENCES TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 10/788,510, filed Feb. 27, 2004 now U.S. Pat. No. 7,331,783, which is a continuation of U.S. application Ser. No. 10/133,155, filed Apr. 26, 2002 (now U.S. Pat. No. 6,786,721), which is a continuation of U.S. application Ser. No. 09/169,036, filed Oct. 8, 1998 (now U.S. Pat. No. 6,450,807), which is a continuation-in-part of PCT Application No. PCT/US98/12861, filed on Jun. 19, 1998, which claims priority from U.S. patent application Ser. No. 08/947,080, filed on Oct. 8, 1997 (now U.S. Pat. No. 5,975,893), which claims priority from U.S. Provisional Application No. 60/050,342, filed on Jun. 20, 1997.

BACKGROUND OF THE INVENTION

The present invention is related generally to the field of orthodontics, and more particularly to a system and a method for gradually repositioning teeth.

A fundamental objective in orthodontics is to realign a patient's teeth to positions where the teeth function optimally and aesthetically. Typically, appliances such as braces are applied to the teeth of the patient by a treating orthodontist. Each appliance exerts continual forces on the teeth which gradually urge the teeth toward their ideal positions. Over a period of time, the orthodontist adjusts the appliances to move the teeth toward their final destination.

The process of attaching the braces to teeth is tedious and painful. Additionally, each visit to the orthodontist is time consuming and expensive. The process is further complicated by uncertainties in determining a final arrangement for each tooth. Generally, the final tooth arrangement is determined by the treating orthodontist who writes a prescription. Traditionally, the prescription is based on the orthodontist's knowledge and expertise in selecting the intended final position of each tooth and without a precise calculation of forces being exerted on the teeth when they contact each other.

BRIEF SUMMARY OF THE INVENTION

The invention provides a method for fitting a set of upper and lower teeth in a masticatory system of a patient. The method generates a computer representation of the masticatory system of the patient; and determines an occlusion from the computer representation of the masticatory system.

Implementations of the invention include one or more of the following. The occlusion may be a static occlusion, which is determined by modeling an ideal set of teeth; automatically applying the ideal set of teeth to the computer representation of the masticatory system of the patient; and optimizing the position of the patient's teeth to fit the ideal set of teeth. The modeling step may select one or more arch forms specifying the ideal set of teeth. The applying step may include registering a model of the upper and lower teeth with a model of the masticatory system; simulating the motion of the jaws to generate contact data between the upper and lower teeth; and placing the tooth in a final position based on the contact data. The model may be registered using X-ray data, computed tomography data, or data associated with a mechanical model. The simulating step may apply kinematics to the model of the teeth or a constrained motion to the model of the tooth. The placing step may be based on a measure of undesirability to the contacts. The position of the tooth may be determined according to the measure of undesirability, such as by minimizing the measure of undesirability. The measure of undesirability may be a function of one or more of Peer Assessment Rating (PAR) metrics, distance-based metrics and shape-based metrics. The simulating step may provide a library of motions with protrusive motions, lateral motions, or tooth-guided motions. Physical forces may be applied to the patient's jaws. The computer representation of the masticatory system may be updated with new patient data. The new patient data may be used with the old data in applying a final position transform to the second teeth model. The matching step may compare correspondences between the first and second teeth models. The correspondences include feature correspondences. The final position transform may include information from a new prescription.

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Other implementations include one or more of the following. The occlusion determining step includes determining one or more indices based on the tooth position; determining an optimality index from the indices; and setting the tooth according to the optimality index. The optimality determining step includes minimizing the optimality index. The indices may be based on a Peer Assessment Rating (PAR) index, a distance metric, or a shape metric. The shape metric may be derived from an arch. The indices may be based on an occlusional index or an orthodontic index. The setting of the teeth may be based on a correspondence of tooth features, including a correspondence of tooth cusps, tooth fossae, or tooth ridges. The optimality index may be optimized using one of simulated annealing technique, hill climbing technique, best-first technique and heuristics technique. The implementation may determine whether a tooth movement reduces the index. The tooth movement may be made along each major axis and may include rotations. The tooth position may be updated if the tooth movement reduces the index.

In a second aspect, a computer-implemented apparatus defines a fit between a set of upper and lower teeth in a masticatory system of a patient. The apparatus comprises instructions operable to cause a programmable processor to generate a computer representation of the masticatory system of the patient; and determining an occlusion from the computer representation of the masticatory system.

Implementations of this aspect include one or more of the following. The invention may determine a static occlusion through instructions to model an ideal set of teeth; automatically apply the ideal set of teeth to the computer representation of the masticatory system of the patient; and optimize the position of the patient's teeth to fit the ideal set of teeth. The occlusion determining instruction may also include instructions to: determine one or more indices based on the tooth position; determine an optimality index from the indices; and set the tooth according to the optimality index.

In another aspect, a system for defining a fit between a set of upper and lower teeth in a masticatory system of a patient includes a processor; a display device coupled to the processor; and a data storage device coupled to the processor, the data storage device storing instructions operable to cause the processor to generate a computer representation of the masticatory system of the patient and determine an occlusion from the computer representation of the masticatory system.

In another aspect, a system for generating one or more appliances for a patient includes a processor; a display device coupled to the processor; a data storage device coupled to the processor; a scanner coupled to the processor for providing data to model the masticatory system; means for defining a fit between a set of upper and lower teeth in a masticatory system of the patient; and a dental appliance fabrication machine

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coupled to the processor for generating the appliances in accordance with the fit of the teeth.

Advantages of the invention include one or more of the following. When a prescription or other final designation is provided, a computer model can be generated and manipulated to match the prescription. The prescription may be automatically interpreted in order to generate an image as well as a digital data set representing the final tooth arrangement.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational diagram showing the anatomical relationship of the jaws of a patient.

FIG. 2A illustrates in more detail the patient's lower jaw and provides a general indication of how teeth may be moved by the methods and apparatus of the present invention.

FIG. 2B illustrates a single tooth from FIG. 2A and defines how tooth movement distances are determined.

FIG. 2C illustrates the jaw of FIG. 2A together with an incremental position adjustment appliance which has been configured according to the methods and apparatus of the present invention.

FIG. 3 is a block diagram illustrating a process for producing incremental position adjustment appliances.

FIG. 4 is a flow chart illustrating a process for optimizing a final placement of the patient's teeth.

FIG. 5 is a flow chart illustrating a process for performing functional occlusion on the patient's teeth.

FIG. 6 is a flow chart illustrating an optional process for incorporating midtreatment information to the final placement of the patient's teeth.

FIG. 7 is a block diagram illustrating a system for generating appliances in accordance with the present invention.

FIG. 8 shows an exemplary process for fitting the ideal teeth.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a skull 10 with an upper jaw bone 22 and a lower jaw bone 20. The lower jaw bone 20 hinges at a joint 30 to the skull 10. The joint 30 is called temporomandibular joint (TMJ). The upper jaw bone 22 is associated with an upper jaw 101, while the lower jaw bone 20 is associated with a lower jaw 100.

A computer model of the jaws 100 and 101 is generated, and a computer simulation models interactions among the teeth on the jaws 100 and 101. The computer simulation allows the system to focus on motions involving contacts between teeth mounted on the jaws. The computer simulation allows the system to render realistic jaw movements which are physically correct when the jaws 100 and 101 contact each other. The model of the jaw places the individual teeth in a treated position. Further, the model can be used to simulate jaw movements including protrusive motions, lateral motions, and "tooth guided" motions where the path of the lower jaw 100 is guided by teeth contacts rather than by anatomical limits of the jaws 100 and 101. Motions are applied to one jaw, but may also be applied to both jaws. Based on the occlusion determination, the final position of the teeth can be ascertained.

Referring now to FIG. 2A, the lower jaw 100 includes a plurality of teeth 102, for example. At least some of these teeth may be moved from an initial tooth arrangement to a final tooth arrangement. As a frame of reference describing how a tooth may be moved, an arbitrary centerline (CL) may be drawn through the tooth 102. With reference to this centerline (CL), each tooth may be moved in orthogonal direc-

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tions represented by axes 104, 106, and 108 (where 104 is the centerline). The centerline may be rotated about the axis 108 (root angulation) and the axis 104 (torque) as indicated by arrows 110 and 112, respectively. Additionally, the tooth may be rotated about the centerline. Thus, all possible free-form motions of the tooth can be performed.

FIG. 2B shows how the magnitude of any tooth movement may be defined in terms of a maximum linear translation of any point P on a tooth 102. Each point P1 will undergo a cumulative translation as that tooth is moved in any of the orthogonal or rotational directions defined in FIG. 2A. That is, while the point will usually follow a nonlinear path, there is a linear distance between any point in the tooth when determined at any two times during the treatment. Thus, an arbitrary point P1 may in fact undergo a true side-to-side translation as indicated by arrow d1, while a second arbitration point P2 may travel along an arcuate path, resulting in a final translation d2. Many aspects of the present invention are defined in terms of the maximum permissible movement of a point P1 induced on any particular tooth. Such maximum tooth movement, in turn, is defined as the maximum linear translation of that point P1 on the tooth which undergoes the maximum movement for that tooth in any treatment step.

FIG. 2C shows one adjustment appliance 111 which is worn by the patient in order to achieve an incremental repositioning of individual teeth in the jaw as described generally above. The appliance is a polymeric shell having a teeth receiving cavity. This is described in U.S. application Ser. No. 09/169,276, filed Oct. 8, 1998, which claims priority from U.S. Pat. No. 5,975,893, which in turn claims priority from provisional application No. 60/050,352, filed Jun. 20, 1997 (collectively the "prior applications"), the full disclosures of which are incorporated by reference.

As set forth in the prior applications, each polymeric shell may be configured so that its tooth receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth are repositioned from their initial tooth arrangement to a final tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. The adjustment appliances are generated at the beginning of the treatment, and the patient wears each appliance until the pressure of each appliance on the teeth can no longer be felt. At that point, the patient replaces the current adjustment appliance with the next adjustment appliance in the series until no more appliance remains. Conveniently, the appliances are generally not affixed to the teeth and the patient may place and replace the appliances at any time during the procedure. The final appliance or several appliances in the series may have a geometry or geometries selected to overcorrect the tooth arrangement, i.e., have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such overcorrection may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e., to permit some movement of individual teeth back toward their precorrected positions. Overcorrection may also be beneficial to speed the rate of correction, i.e., by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, the use of an appliance can be terminated before the teeth reach the positions defined by the appliance.

The polymeric shell 111 can fit over all teeth present in the upper or lower jaw. Often, only certain one(s) of the teeth will be repositioned while others of the teeth will provide a base or an anchor region for holding the appliance 111 in place as the

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appliance 111 applies a resilient repositioning force against the tooth or teeth to be repositioned. In complex cases, however, multiple teeth may be repositioned at some point during the treatment. In such cases, the teeth which are moved can also serve as a base or anchor region for holding the repositioning appliance.

The polymeric appliance 111 of FIG. 2C may be formed from a thin sheet of a suitable elastomeric polymer, such as Tru-Tain 0.03 in, thermal forming dental material, available from Tru-Tain Plastics, Rochester, Minn. Usually, no wires or other means will be provided for holding the appliance in place over the teeth. In some cases, however, it will be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance 111 so that the appliance can apply an upward force on the tooth which would not be possible in the absence of such an anchor.

FIG. 3 shows a process 200 for producing the incremental position adjustment appliances for subsequent use by a patient to reposition the patient's teeth. As a first step, an initial digital data set (IDDS) representing an initial tooth arrangement is obtained (step 202). The IDDS may be obtained in a variety of ways. For example, the patient's teeth may be scanned or imaged using X-rays, three dimensional X-rays, computer-aided tomographic images or data sets, or magnetic resonance images, among others. The teeth data may be generated by a destructive scanner, as described in the incorporated-by-reference U.S. application Ser. No. 09/169, 276, filed Oct. 8, 1998.

The IDDS is then manipulated using a computer having a suitable graphical user interface (GUI) and software appropriate for viewing and modifying the images. More specific aspects of this process will be described in detail below.

Individual tooth and other components may be segmented or isolated in the model to permit their individual repositioning or removal from the digital model. After segmenting or isolating the components, the user will often reposition the tooth in the model by following a prescription or other written specification provided by the treating professional. Alternatively, the user may reposition one or more teeth based on a visual appearance or based on rules and algorithms programmed into the computer. Once the user is satisfied, the final teeth arrangement is incorporated into a final digital data set (FDDS) (step 204). The FDDS is used to generate appliances that move the teeth in a specified sequence. First, the centers of each tooth model may be aligned using a number of methods. One method is a standard arch. Then, the teeth models are rotated until their roots are in the proper vertical position. Next, the teeth models are rotated around their vertical axis into the proper orientation. The teeth models are then observed from the side, and translated vertically into their proper vertical position. Finally, the two arches are placed together, and the teeth models moved slightly to ensure that the upper and lower arches properly mesh together. The meshing of the upper and lower arches together is visualized using a collision detection process to highlight the contacting points of the teeth.

Based on both the IDDS and the FDDS, a plurality of intermediate digital data sets (INTDDSS) are defined to correspond to incrementally adjusted appliances (step 206). Finally, a set of incremental position adjustment appliances are produced based on the INTDDSS and the FDDS (step 208).

In step 204, final positions for the upper and lower teeth in a masticatory system of a patient are determined by generating a computer representation of the masticatory system. An occlusion of the upper and lower teeth is computed from the computer representation; and a functional occlusion is computed based on interactions in the computer representation of

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the masticatory system. The occlusion may be determined by generating a set of ideal models of the teeth. Each ideal model in the set of ideal models is an abstract model of idealized teeth placement which is customized to the patient's teeth, as discussed below. After applying the ideal model to the computer representation, and the position of the teeth is optimized to fit the ideal model. The ideal model may be specified by one or more arch forms, or may be specified using various features associated with the teeth.

FIG. 4 illustrates a process 300 which optimizes the final placement of the teeth based on teeth features. First, the process 300 automatically or, with human assistance, identifies various features associated with each tooth to arrive at a model of the teeth (step 302). An ideal model set of teeth is then generated either from casts of the patient's teeth or from patients with a good occlusion (step 303).

From step 302, the process 300 positions the model of the teeth in its approximate final position based on a correspondence of features to the ideal model (step 304). In that step, each tooth model is moved so that its features are aligned to the features of a corresponding tooth in the ideal model. The features may be based on cusps, fossae, ridges, distance-based metrics, or shape-based metrics. Shape-based metrics may be expressed as a function of the patient's arches, among others.

For example, cusp features associated with each tooth may be used. Cusps are pointed projections on the chewing surface of a tooth. In a detection stage, a possible cusp is viewed as an "island" on the surface of the tooth, with the candidate cusp at the highest point on the island. "Highest" is measured with respect to the coordinate system of the model, but could just as easily be measured with respect to the local coordinate system of each tooth. The set of all possible cusps is determined by looking for all local maxima on the tooth model that are within a specified distance of the top of the bounding box of the model. First, the highest point on the model is designated as the first candidate cusp. A plane is passed through this point, perpendicular to the direction along which the height of a point is measured. The plane is then lowered by a small predetermined distance along the Z axis. Next, all vertices connected to the tooth and which are above the plane and on some connected component are associated with the candidate cusp as cusps. This step is also referred to as a flood fill step. From each candidate cusp point, outward flooding is performed, marking each vertex on the model visited in this manner as part of the corresponding candidate cusp. After the flood fill step is complete, every vertex on the model is examined. Any vertex that is above the plane and has not been visited by one of the flood fills is added to the list of candidate cusps. These steps are repeated until the plane has traveled a specified distance.

After the detection stage, the cusp detection process may include a rejection stage where local geometries around each of cusp candidates are analyzed to determine if they possess non-cusp-like features. Cusp candidates that exhibit non-cusp-like features are removed from the list of cusp candidates. Various criteria may be used to identify non-cusp-like features. According to one test, the local curvature of the surface around the cusp candidate is used to determine whether the candidate possesses non-cusp-like features. Alternatively, a measure of smoothness is computed based on the average normal in an area around the candidate cusp. If the average normal deviates from the normal at the cusp by more than a specified amount, the candidate cusp is rejected.

Next, the process 300 computes an orthodontic/occlusion index (step 306). One index which may be used is the PAR

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(Peer Assessment Rating) index. In addition to PAR, other metrics such as shape-based metrics or distance-based metrics may be used.

The PAR index identifies how far a tooth is from a good occlusion. A score is assigned to various occlusal traits which make up a malocclusion. The individual scores are summed to obtain an overall total, representing the degree a case deviates from normal alignment and occlusion. Normal occlusion and alignment is defined as all anatomical contact points being adjacent, with a good intercuspal mesh between upper and lower buccal teeth, and with nonexcessive overjet and overbite.

In PAR, a score of zero would indicate good alignment, and higher scores would indicate increased levels of irregularity. The overall score is recorded on pre- and posttreatment dental casts. The difference between these scores represents the degree of improvement as a result of orthodontic intervention and active treatment. The eleven components of the PAR Index are: upper right segment; upper anterior segment; upper left segment; lower right segment; lower anterior segment; lower left segment; right buccal occlusion; overjet; overbite; centerline; and left buccal occlusion. In addition to the PAR index, other indices may be based on distances of the features on the tooth from their ideal positions or ideal shapes.

From step 306, the process 300 determines whether additional index-reducing movements are possible (step 308). Here, all possible movements are attempted, including small movements along each major axis as well as small movements with minor rotations. An index value is computed after each small movement and the movement with the best result is selected. In this context, the best result is the result that minimizes one or more metrics such as PAR-based metrics, shape-based metrics or distance-based metrics. The optimization may use a number of techniques, including simulated annealing technique, hill climbing technique, best-first technique, Powell method, and heuristics technique, among others. Simulated annealing techniques may be used where the index is temporarily increased so that another path in the search space with a lower minimum may be found. However, by starting with the teeth in an almost ideal position, any decrease in the index should converge to the best result.

In step 308, if the index can be optimized by moving the tooth, incremental index-reducing movement inputs are added (step 310) and the process loops back to step 306 to continue computing the orthodontic/occlusion index. Alternatively, in the event that the index cannot be optimized any more, the process 300 exits (step 312).

Turning now to FIG. 5, a process 320 for performing functional occlusion is shown. Functional occlusion is a process for determining how well the teeth fit together when the jaws move. The process 320 first acquires tooth/arch/jaw registration. This may be done using conventional techniques such as X-ray, a computer tomography, or a mechanical device such as a face bow transfer (322).

After acquiring the registration information, the process 320 places digital dental models of the teeth in a digital articulation simulator (step 324). The articulation simulator allows a subset of jaw movements such as bite-movements to be simulated, as described below.

From step 324, the process 320 simulates jaw motions (step 326). A simplified set of movement physics (kinematics) is applied to the dental models. The process 320 performs a simulation using a simplified set of interacting forces on the jaws 100 and 101 in relation to one another. The simplified physical simulation allows the system to focus on motions involving much contact between the jaws. The physical simu-

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lation allows the system to render realistic physically correct jaw movements when the jaws 100 and 101 come into contact with each other.

A range of simulated motion may be supplied using a library of motions. One typical motion supplied by the library is a protrusive motion where the lower jaw 101 is moved forward and backward to bring the front teeth on both jaws into contact with each other. Another motion is a lateral motion found in food chewing. The lateral motion involves moving the jaws 100 and 101 side to side. Other motions that may be supplied in the library include motions that are "tooth guided" where the path of the lower jaw 100 is guided by the teeth in contact with each other.

Next, the process 320 adjusts the final position based on contacts observed during the simulation of motions in step 326 (step 328). The result of the simulation is analyzed, the position of each tooth can be adjusted if contacts associated with that tooth are deemed excessive.

Finally, based on the contact data generated, the process 320 determines whether additional motion simulations need to be done. The motion simulation may be rerun until the contacts associated with each tooth are acceptable to the treating orthodontist. The tooth model manipulation process can be done subjectively, i.e., the user may simply reposition teeth in an aesthetically and/or therapeutically desired manner based on observations of the final position or based on the simulation of contacts. Alternatively, rules and algorithms may be used to assist the user in repositioning the teeth based on the contacts. If the simulation needs to be repeated, the process loops back to step 326 (step 330). Alternatively, the process exits (step 332).

FIG. 6 shows an optional process of 340 of incorporating midtreatment information to the final positioning process. First, a digital model incorporating dental information associated with the patient is generated from a scan of the patient's teeth (step 342). The scan may be performed using casts, X-rays or any of the conventional scanning methods.

Next, the digital model is segmented into one model for each tooth (step 344). Each tooth is then matched against a model associated with a prior scan developed at the beginning of the treatment plan (step 346). The matching process is based on matching corresponding points between the current scan and the prior scan of the teeth. In most cases, the teeth segmented from the current scan retain the shapes determined at the beginning of the treatment plan, and the matching process is easy because the models should be similar to each other.

A final position transform is then applied to the new teeth model (step 348). The final position and specification from the prior model is copied to the current model of the patient, and the final position is adjusted based on the new models, the new X-ray information or a new prescription (step 350). Step 350 basically involves rerunning the minimization process 300 (FIG. 4) described previously with the new information, which may be a slight change in the model, a change in the X-ray scan, or a change the prescription. Finally, the process 340 exits (step 352).

FIG. 7 is a simplified block diagram of a data processing system 500. Data processing system 500 typically includes at least one processor 502 which communicates with a number of peripheral devices over bus subsystem 504. These peripheral devices typically include a storage subsystem 506 (memory subsystem 508 and file storage subsystem 514), a set of user interface input and output devices 518, and an interface to outside networks 516, including the public switched telephone network. This interface is shown schematically as "Modems and Network Interface" block 516,

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and is coupled to corresponding interface devices in other data processing systems over communication network interface 524. Data processing system 500 may include a terminal or a low-end personal computer or a high-end personal computer, workstation or mainframe.

The user interface input devices typically include a keyboard and may further include a pointing device and a scanner. The pointing device may be an indirect pointing device such as a mouse, trackball, touchpad, or graphics tablet, or a direct pointing device such as a touchscreen incorporated into the display. Other types of user interface input devices, such as voice recognition systems, may be used.

User interface output devices may include a printer and a display subsystem, which includes a display controller and a display device coupled to the controller. The display device may be a cathode ray tube (CRT), a flat-panel device such as a liquid crystal display (LCD), or a projection device. The display subsystem may also provide nonvisual display such as audio output.

Storage subsystem 506 maintains the basic programming and data constructs that provide the functionality of the present invention. The software modules discussed above are typically stored in storage subsystem 506. Storage subsystem 506 typically comprises memory subsystem 508 and file storage subsystem 514.

Memory subsystem 508 typically includes a number of memories including a main random access memory (RAM) 510 for storage of instructions and data during program execution and a read only memory (ROM) 512 in which fixed instructions are stored. In the case of Macintosh-compatible personal computers the ROM would include portions of the operating system; in the case of IBM-compatible personal computers, this would include the BIOS (basic input/output system).

File storage subsystem 514 provides persistent (nonvolatile) storage for program and data files, and typically includes at least one hard disk drive and at least one floppy disk drive (with associated removable media). There may also be other devices such as a CD-ROM drive and optical drives (all with their associated removable media). Additionally, the system may include drives of the type with removable media cartridges. The removable media cartridges may, for example be hard disk cartridges, such as those marketed by Syquest and others, and flexible disk cartridges, such as those marketed by Iomega. One or more of the drives may be located at a remote location, such as in a server on a local area network or at a site on the Internet's World Wide Web.

In this context, the term "bus subsystem" is used generically so as to include any mechanism for letting the various components and subsystems communicate with each other as intended. With the exception of the input devices and the display, the other components need not be at the same physical location. Thus, for example, portions of the file storage system could be connected over various local-area or wide-area network media, including telephone lines. Similarly, the input devices and display need not be at the same location as the processor, although it is anticipated that the present invention will most often be implemented in the context of PCs and workstations.

Bus subsystem 504 is shown schematically as a single bus, but a typical system has a number of buses such as a local bus and one or more expansion buses (e.g., ADB, SCSI, ISA, EISA, MCA, NuBus, or PCI), as well as serial and parallel ports. Network connections are usually established through a device such as a network adapter on one of these expansion buses or a modem on a serial port. The client computer may be a desktop system or a portable system.

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Scanner 520 is responsible for scanning casts of the patient's teeth obtained either from the patient or from an orthodontist and providing the scanned digital data set information to data processing system 500 for further processing.

5 In a distributed environment, scanner 520 may be located at a remote location and communicate scanned digital data set information to data processing system 500 over network interface 524.

Fabrication machine 522 fabricates dental appliances based on intermediate and final data set information received from data processing system 500. In a distributed environment, fabrication machine 522 may be located at a remote location and receive data set information from data processing system 500 over network interface 524.

15 Various alternatives, modifications, and equivalents may be used in lieu of the above components. Although the final position of the teeth may be determined using computer-aided techniques, a user may move the teeth into their final positions by independently manipulating one or more teeth while satisfying the constraints of the prescription.

20 Additionally, the techniques described here may be implemented in hardware or software, or a combination of the two. The techniques may be implemented in computer programs executing on programmable computers that each includes a 25 processor, a storage medium readable by the processor (including volatile and nonvolatile memory and/or storage elements), and suitable input and output devices. Program code is applied to data entered using an input device to perform the functions described and to generate output information. The 30 output information is applied to one or more output devices.

Each program can be implemented in a high level procedural or object-oriented programming language to operate in conjunction with a computer system. However, the programs can be implemented in assembly or machine language, if desired. In any case, the language may be a compiled or interpreted language.

35 Each such computer program can be stored on a storage medium or device (e.g., CD-ROM, hard disk or magnetic diskette) that is readable by a general or special purpose programmable computer for configuring and operating the computer when the storage medium or device is read by the computer to perform the procedures described. The system also may be implemented as a computer-readable storage medium, configured with a computer program, where the storage medium so configured causes a computer to operate in a specific and predefined manner.

40 FIG. 8 shows an exemplary process for fitting the ideal teeth. First, the process provides a static occlusion determined from a computer representation of the masticatory system. Next, the process models an ideal set of teeth and automatically applies the ideal set of teeth to the computer representation of the masticatory system of the patient. Further, the process optimizes the position of the patient's teeth to fit the ideal set of teeth.

45 45 Further, while the invention has been shown and described with reference to an embodiment thereof, those skilled in the art will understand that the above and other changes in form and detail may be made without departing from the spirit and scope of the following claims.

What is claimed is:

1. A method of planning orthodontic treatment of a patient comprising use of incremental tooth repositioning appliances, the method comprising:
receiving an initial digital data set representing an initial arrangement of the patient's teeth;
producing a final digital data set representing the patient's teeth in a desired or prescribed arrangement;

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producing a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from the initial arrangement toward the final arrangement.

2. The method of claim 1, wherein the initial digital data set is generated from a scan of the patient's teeth or impression thereof.

3. The method of claim 1, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

4. The method of claim 1, wherein the appliances are generated based on at least some of the intermediate digital data sets and wherein the plurality of intermediate digital data sets are produced prior to successively applying appliances to the patient's teeth.

5. The method of claim 1, further comprising providing a plurality of the intermediate digital data sets to a fabrication operation for fabrication of a series of successive tooth repositioning appliances.

6. The method of claim 5, wherein the providing comprises transmitting the digital data sets over a network to the remote location comprising a fabrication machine.

7. An orthodontic treatment plan for repositioning a patient's teeth using incremental tooth repositioning appliances, the treatment plan residing on a computer readable storage media and comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a final arrangement representing the patient's teeth in a desired or prescribed arrangement.

8. The orthodontic treatment plan of claim 7, wherein the intermediate digital data sets for different orthodontic treatment stages are configured for facilitating fabrication of shell appliances for a corresponding treatment stage.

9. The orthodontic treatment plan of claim 8, wherein the shell appliances comprise a plurality of successive appliances having teeth receiving cavities, and wherein cavities of at least two successive appliances have different geometries shaped to receive and reposition the patient's teeth.

10. A method for generating appliances for repositioning a patient's teeth, comprising:

receiving an orthodontic treatment plan for repositioning a patient's teeth, the treatment plan comprising a plurality of intermediate digital data sets representing intermediate arrangements of the patient's teeth, wherein at least some of the intermediate tooth arrangements represent different orthodontic treatment stages as the patient's teeth are moved from an initial arrangement toward a

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final arrangement representing the patient's teeth in a desired or prescribed arrangement; generating a patient removable appliance for each of at least two of the intermediate arrangements, each patient removable appliance having cavities and wherein the cavities of appliances for the at least two intermediate arrangements have different geometries shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.

11. The method of claim 10, wherein the patient removable appliances for each of the at least two intermediate arrangements are generated prior to successively applying the appliances to the patient's teeth.

12. The method of claim 10, wherein the orthodontic treatment plan is transmitted from a remote location.

13. An improved method for repositioning teeth using a plurality of appliances comprising polymeric shells having teeth receiving cavities shaped to receive and resiliently reposition a patient's teeth, wherein an improvement comprises modeling prior to a stage of treatment a plurality of different teeth-receiving cavity geometries for at least three appliances that when worn successively by the patient reposition the patient's teeth toward a final tooth arrangement, the at least three appliances comprising at least two successive intermediate appliances having different cavity geometries, and wherein said stage of treatment comprises successively applying any of the at least three appliances to the patient's teeth, wherein each of the different teeth-receiving cavity geometries for the at least three appliances correspond to different arrangements of teeth.

14. The method of claim 13, wherein the successive intermediate appliances are immediately successive.

15. The method of claim 13, wherein the modeling occurs before fabricating at least some of the appliances.

16. The method of claim 13, further comprising fabricating the at least two successive intermediate appliances after modeling the cavity geometries for at the at least three appliances.

17. A system for repositioning teeth a patient's teeth, comprising a plurality of incremental position adjustment appliances configured for delivery to the patient prior to a stage of treatment, the plurality of appliances comprising a patient removable appliance for each of at least two different intermediate arrangements for repositioning the patient's teeth toward a final position, each patient removable appliance having teeth receiving cavities and wherein the cavities of two different successive appliances of the plurality have different geometries corresponding to different arrangements of teeth and shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, wherein said stage of treatment comprises successively applying the appliances to the patient's teeth.

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